IMMULITE® 2000/2500 Automated Immunoassay System

Service Manual

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IMMULITE® 2000/2500 Service Manual

Chapter 1: General Information

1.1 DPC and IMMULITE® 2000/2500 History

The company that conceived the IMMULITE and IMMULITE 2000 was founded in 1987 by Dr. Arthur Babson and began operations in 1988 in a rented classroom of the old Chester, NJ school building. The company, which started as Babson Technologies, was renamed Pegasus Technologies, and, in 1990, was renamed again to Cirrus Diagnostics. In 1992, the company became DPC Cirrus, Inc.

By the end of 1988, a breadboard immunoassay Analyzer was complete. It was on this Instrument that many of the basic concepts of IMMULITE I were developed and tested.

In 1990, three prototypes, known as the "A" series IMMULITE I Systems, were built. One of these was demonstrated at the AACC meeting in July of 1990. Although these Systems incorporated many of the functions of the breadboard, their layout was a radical departure. In the next year and a half, these Instruments were used as "workhorses" to further develop the hardware, software, and chemistry. At that time, the company had approximately 20 people and had expanded its operations to four classrooms in the school building.

During the last half of 1991, 12 "B" series IMMULITE I Systems were produced. These were to be used for beta site placements and in-house research and development. On July 17, 1991, Instrument "B1" was placed in Morristown Memorial Hospital as the company's first beta site Instrument. During the next five months, four more Instruments were placed at beta sites in New York City and Washington, DC.

On March 23, 1992, Instrument "B2" was placed at Diagnostic Products Corporation (DPC) for evaluation. DPC liked the IMMULITE so much that, 60 days later, Cirrus Diagnostics became DPC/Cirrus, a wholly-owned subsidiary of DPC.

During the last half of 1992, 25 "C" series IMMULITE I Systems were produced by an Instrumentation manufacturing company located very close to DPC/Cirrus. At that time, DPC/Cirrus was still located in the school building in Chester, NJ, employed 33 people, and occupied 9 classrooms.

In December 1992, DPC/Cirrus moved into a new building in Randolph, NJ and began its in-house manufacture of the IMMULITE I System, beginning with the "D" series.

Development of the IMMULITE 2000 System began in 1994. In 1996, an integrated breadboard for this Instrument was complete and, by the latter half of 1996, six engineering prototypes had been built. Production of the IMMULITE 2000 System began in May 1997.

In autumn 2001, DPC/Cirrus became DPC Instrument Systems Division and in December of the same year, the organization moved into its new facility in Flanders, NJ. In-house manufacture of the IMMULITE and IMMULITE 2000 systems continued with the "L" and "F" series respectively.

Development of the IMMULITE 2500 System began in 2000. In 2002, an integrated breadboard was completed. By the end of 2003, 35 manufacturing prototypes were built. By early 2004, full production of the IMMULITE 2500 began. This system introduced Logic Driven Incubation to our line of products.

1.2 How To Use This Manual

This manual contains the basic information necessary for after-sales service of the DPC IMMULITE 2000/2500 Analyzer System. The information is vital to the service person for maintaining high quality and reliable performance of the System.

This manual is applicable to all IMMULITE 2000/2500 Analyzer Systems having Serial number B0001 or later.

The IMMULITE 2000/2500 Service Manual is designed to be used *only* by authorized IMMULITE 2000/2500 service personnel. Authorized service personnel are knowledgeable in the areas of electronics, mechanical devices, and basic computer technology, and have attended the IMMULITE 2000/2500 Service Training Seminar.

Each area or module of the System is covered in this manual. This information includes descriptions, possible adjustments, diagnostic programs, problems, and probable causes. Highly refined troubleshooting techniques, at the component level on the circuit boards, are not covered here because the required expertise and investment in special tools and equipment would make such tasks uneconomical.

The chosen method of locating the cause of the malfunction and repairing the instrument is a thorough understanding of the IMMULITE 2000/2500, based on information contained in this manual, in the IMMULITE 2000/2500 Operator's Manual, and in the Service Information Bulletins. A lesser understanding will slow servicing and could result in expensive and even dangerous mistakes. Since knowledge of the IMMULITE 2000/2500 is the best "tool" for diagnosing problems, this manual takes more of an *educational* approach.

<u>Note</u>: Information in this manual is subject to change as System elements are improved (and possibly redesigned) and as better, more efficient procedures are developed. All relevant information in such cases will be supplied in Service Information Bulletins.

When diagnosing a problem on the IMMULITE 2000/2500, keep the following points in mind:

- 1. Aside from the software, the IMMULITE 2000/2500 is similar to any other electromechanical device.
- 2. When diagnosing a problem, follow the Troubleshooting Techniques in the Troubleshooting section of this manual. This section contains proven techniques, which, if applied correctly, will significantly reduce the time spent on diagnosing System problems.
- **3.** Repair the problem—*not* the symptom.
- **4.** Replace only what is necessary.

1.3 Product Descriptions

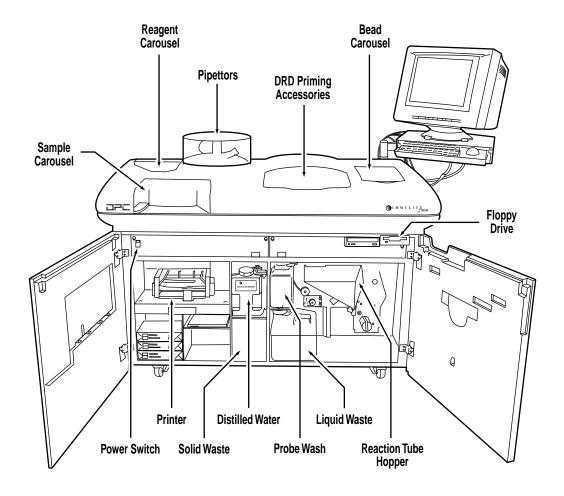
1.3.1 IMMULITE 2000

The IMMULITE 2000 Automated Immunoassay Analyzer is a random-access Instrument which performs chemiluminescent immunoassays. The System is intended to assay a broad range of analytes in serum, plasma, and urine. Analysis of serum, plasma, or urine analytes on the IMMULITE 2000 is intended to provide information related to *in vitro* diagnostic procedures when used in conjunction with specific, barcoded IMMULITE 2000 beads and reagents.

The IMMULITE 2000 System utilizes specific, antibody-coated beads, as the solid phase, in a specially designed Reaction Tube. The Reaction Tube serves as the vessel in which incubation of the immune reaction, wash, and signal development takes place. Light emission from the chemiluminescent substrate, reacting with the enzyme conjugate bound to the bead, is proportional to the amount of analyte originally present in the patient specimen.

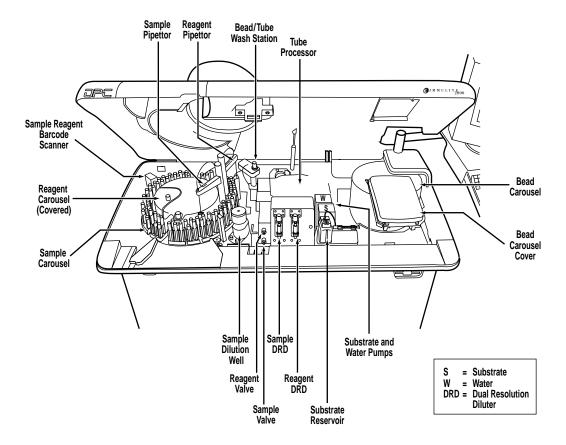
The IMMULITE 2000 is totally automated in its handling of clinical sample and conjugate reagents and in its handling of incubation, washing, and substrate addition. The Photomultiplier Tube (PMT) detects light emission and an integral computer generates hard copy for each sample. A full view of the Instrument is shown in Figure 1.

Figure 1 Full Instrument View



A view of the Instrument with its main cover open is shown in Figure 2.

Figure 2 Instrument – View Under Main Cover



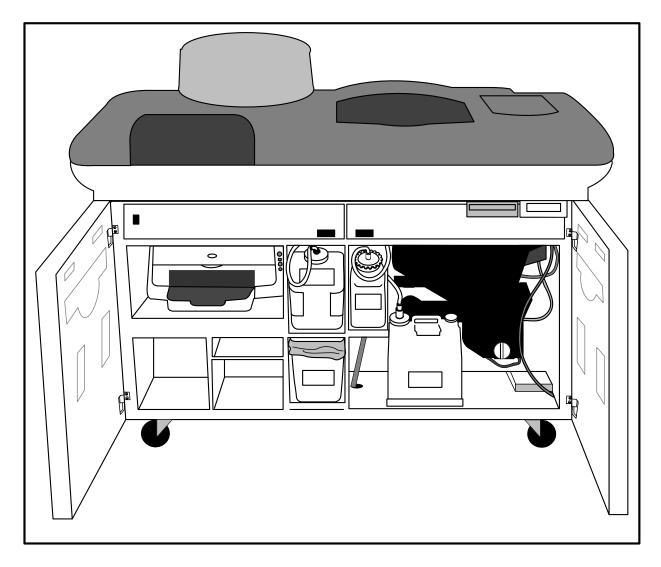
1.3.2 IMMULITE 2500

The IMMULITE 2500 Automated Immunoassay System is a random-access Instrument which performs chemiluminescent immunoassays. Twin oval belts rotate tubes back and forth providing constant access to all incubator positions. Based on this new technology, assay incubation times are dependent on chemistry kinetics rather than 30-minute incubation cycles. The System is intended to assay a broad range of analytes in serum, plasma, and urine. Analysis of serum, plasma, or urine analytes on the IMMULITE 2500 is intended to provide information related to *in vitro* diagnostic procedures when used in conjunction with specific, barcoded IMMULITE 2500 beads and reagents.

The IMMULITE 2500 System utilizes specific, antibody-coated beads, as the solid phase, in a specially designed Reaction Tube. The Reaction Tube serves as the vessel in which incubation of the immune reaction, wash, and signal development takes place. Light emission from the chemiluminescent substrate, reacting with the enzyme conjugate bound to the bead, is proportional to the amount of analyte originally present in the patient specimen.

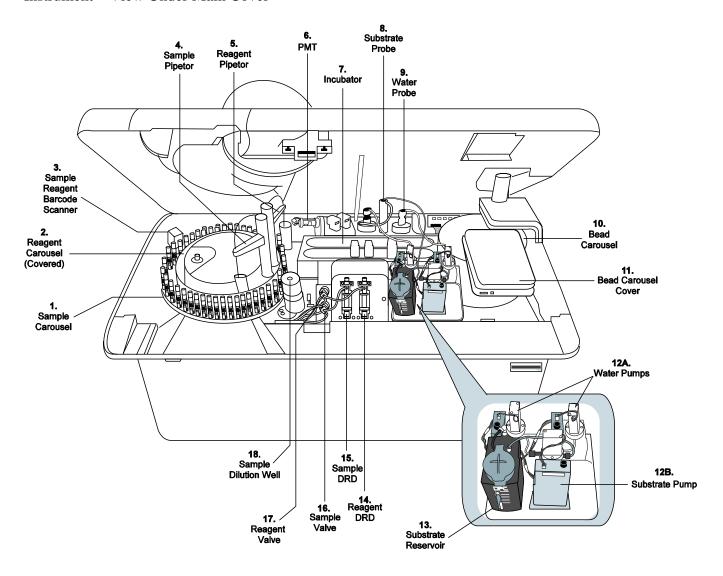
The IMMULITE 2500 is totally automated in its handling of clinical sample and conjugate reagents and in its handling of incubation, washing, and substrate addition. The Photomultiplier Tube (PMT) detects light emission and an integral computer generates hard copy for each sample. A full view of the Instrument is shown in Figure 3.

Figure 3 Instrument – Front Doors Open



A view of the Instrument with its main cover open is shown in Figure 4.

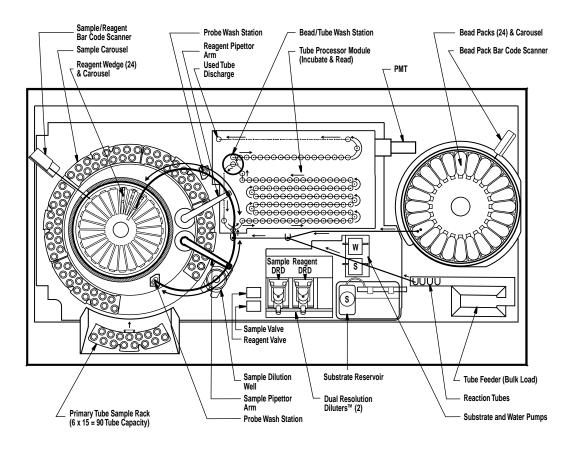
Figure 4 Instrument – View Under Main Cover



1.4 System Components

1.4.1 IMMULITE 2000 System Components

Figure 3 IMMULITE 2000 System Components



Components Listing

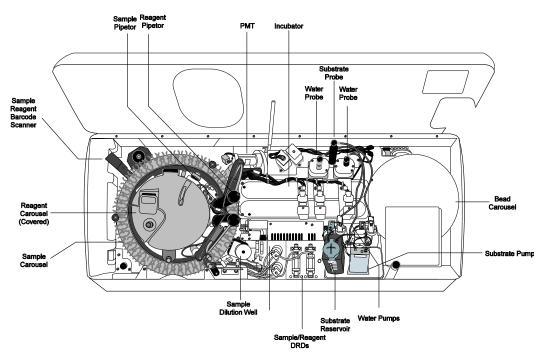
The following is a list of the IMMULITE 2000 System Components.

- Sample Carousel
 - accommodates six easily-removable racks
 - each rack holds 15 specimen or diluent tubes
 - permits easy reading of vertically-oriented barcodes on all tubes
- o Sample Arm
 - simultaneously actuates a probe both vertically and horizontally
- Dilution Well
 - mixes quantities of specimen, diluent, and water by agitation
 - disposes of excess mixture by high-speed rotation

- o Reagent Carousel
 - accommodates 24 Reagent Wedges, each capable of holding three different reagents
 - is housed within a refrigerated chamber, maintained at $4^{\circ}\text{C} 8^{\circ}\text{C}$.
- Reagent Arm
 - simultaneously actuates an arm probe both vertically and rotationally
- Sample Barcode Reader
 - reads specimen, diluent, and reagent barcodes
 - programmable to recognize multiple barcode symbologies
- Tube Feeder
 - accepts reaction tubes in bulk
 - orients reaction tubes
 - delivers reaction tubes first to the bead dispenser, then to the pipetting position
- Bead Carousel
 - accommodates 24 Bead Packs, each capable of holding 200 beads
 - maintained at <20% RH within a dehumidified chamber
 - dispenses beads, one at a time, from any Bead Pack, as needed
- Tube Processor, which comprises the following:
 - Transfer chain
 - Incubator chain
 - Shaker (reaction tube shaker bars)
 - Luminometer shuttle
 - Tube lifter
 - Tube wash station (high speed spinner)
 - Luminometer chain
 - Substrate heater
 - Incubator and Luminometer block heaters
 - Shutter
 - Attenuator disk
 - Read station (with PMT)
- o Fluidics System
 - consists of pumps, valves, tubing, and reservoirs
 - provides for transfer and disposal of fluids throughout the Instrument
- Control System
 - consists of motor controllers, cabling, power supplies, log circuitry, and software
 - controls and coordinates all Instrument activities
- User Interface
 - consists of logic circuitry, cabling, user input/output devices, and software
 - · accepts user commands and displays the results of those commands

1.4.2 IMMULITE 2500 System Components

Figure 4 IMMULITE 2500 System Components



Components Listing

The following is a list of the IMMULITE 2500 System Components.

- o Sample Carousel
 - accommodates six easily-removable racks
 - each rack holds 15 specimen or diluent tubes
 - permits easy reading of vertically-oriented barcodes on all tubes
- o Sample Arm
 - simultaneously actuates a probe both vertically and horizontally
- o Dilution Well
 - mixes quantities of specimen, diluent, and water by agitation
 - disposes of excess mixture by high-speed rotation
- Reagent Carousel
 - accommodates 24 Reagent Wedges, each capable of holding three different reagents
 - is housed within a refrigerated chamber, maintained at $4^{\circ}C 8^{\circ}C$.
- o Reagent Arm
 - simultaneously actuates an arm probe both vertically and rotationally

Sample Barcode Reader

- reads specimen, diluent, and reagent barcodes
- programmable to recognize multiple barcode symbologies

Tube Feeder

- accepts reaction tubes in bulk
- orients reaction tubes
- delivers reaction tubes first to the bead dispenser, then to the pipetting position

Bead Carousel

- accommodates 24 Bead Packs, each capable of holding 200 beads
- maintained at <20% RH within a dehumidified chamber
- dispenses beads, one at a time, from any Bead Pack, as needed

• Tube Processor, which comprises the following:

- Incubator belts 1 and 2
- Tube wash station (high speed spinner)
- Luminometer Belt
- Substrate heater
- Incubator and Luminometer block heaters
- Luminometer disk
- Attenuator disk
- Read station (with PMT)

o Fluidics System

- consists of pumps, valves, tubing, and reservoirs
- provides for transfer and disposal of fluids throughout the Instrument

Control System

- consists of motor controllers, cabling, power supplies, log circuitry, and software
- controls and coordinates all Instrument activities

User Interface

- consists of logic circuitry, cabling, user input/output devices, and software
- accepts user commands and displays the results of those commands

1.5 How It Works

The system is built around a proprietary Reaction Tube that rapidly and efficiently washes an antibody-coated bead by spinning the Reaction Tube on its vertical axis. Sample, excess reagent, and wash solution are spun out of the tube.

The IMMULITE 2000/2500 System utilizes assay-specific, antibody-coated polystyrene beads as the solid phase. The bead is housed in a specially designed Reaction Tube. This Reaction Tube serves as the reaction vessel for the immune reaction, the incubation and washing processes, and the signal development. Light emission from the chemiluminescent substrate, reacting with the enzyme conjugate (bound to the bead), is proportional to the amount of analyte originally present in the patient sample.

The IMMULITE 2000 System automates the handling of samples and conjugates, the incubation and washing processes, and the addition of substrate. After the sample has been incubated with the alkaline phosphatase reagent, spinning the Reaction Tube at a high speed on its vertical axis efficiently washes the bead and Reaction Tube. Four or more separate washes can be accomplished within seconds, allowing the Reaction Tubes to be processed sequentially and with uniform timing. The bead is left with no residual, unbound label. The bound label is then quantified with a dioxetane substrate which produces light during hydrolysis. A photomultiplier tube detects light emission and, for each sample, printed reports are generated.

The IMMULITE 2500 System automates the handling of samples and conjugates. Twin oval belts rotate tubes back and forth providing constant access to all incubator positions. Based on this new technology, assay incubation times are dependent on chemistry kinetics rather than 30-minute incubation cycles. There are dual incubators and wash stations on the IMMULITE 2500. If Incubator 1 shuts down, tests processed in Incubator 2 continue to completion. If either Wash Station shuts down, the other Wash Station can continue at reduced throughput. After the sample has been incubated with the alkaline phosphatase reagent, spinning the Reaction Tube at a high speed on its vertical axis efficiently washes the bead and Reaction Tube. After washing, the bead is left with no residual, unbound label. The bound label is then quantified with a dioxetane substrate, which produces light during hydrolysis. A photomultiplier tube detects light emission and, for each sample, printed reports are generated.

1.6 Trademark Conventions

Trademarked names may be used throughout this manual. Rather than using a symbol (TM or $^{\circledR}$) at every occurrence, we state herein that we are using such names only in an editorial fashion, and to the benefit of the trademark owner, with no intention of infringement.

1.7 Safety Considerations

All service personnel must read and understand these safety procedures before working with this system.

WARNING and CAUTION instructions must be observed during servicing of the IMMULITE 2000/2500. These are defined as follows:

- <u>WARNING</u>: Issued when failure to observe its instructions can result in injury or death to the operator or service personnel.
- <u>CAUTION</u>: Issued when failure to observe its instructions can result in permanent damage to the equipment.

WARNINGS

The following WARNINGS are provided to avoid bodily injury:

- 1. The IMMULITE 2000/2500 requires a dedicated 220V line. Application of the incorrect AC power input voltage could cause an explosion, fire, or electrical shock that may injure the operator or permanently damage the equipment.
- 2. Ensure that the AC power receptacle has the voltage and power rating specified for the Instrument. Use of an AC power receptacle with incorrect voltage and power rating could overload a circuit and produce fire and electrical shock hazards.
- **3.** Never use a three-conductor-to-two-conductor adapter to connect primary AC power to any of the IMMULITE 2000/2500 components or test equipment. Use of an adapter disconnects the utility ground and allows reversal of the live and neutral lines. A severe shock hazard could exist which could cause severe injury or death. Use only a three-conductor connector and three-conductor ground receptacle to connect primary AC power to the IMMULITE 2000/2500 and its components.
- **4.** Do not assume that AC power is removed from equipment when the power switch is off. Some portions of the power supply chassis are HOT whenever the unit is connected to the AC power receptacle.
- **5.** Do not assume that all AC power is removed from the equipment when any one of the IMMULITE 2000/2500 fuses blows. Before attempting to replace fuses, always switch off the AC power and disconnect the power cable from the IMMULITE 2000/2500.
- **6.** Since the Instrument is used with patient specimens, take all necessary precautions to avoid transfer of infectious diseases.

CAUTIONS

The following CAUTIONS are provided to avoid Instrument damage:

- 1. Use replacement fuses with the required current rating and specifications. Makeshift fuses, fuses with higher current rating than specified, or short-circuiting of fuse holders may cause fire or damage the Instrument. Replaceable fuses on the IMMULITE 2000/2500 can be accessed only by qualified service people; they are inaccessible to users.
- 2. Do not remove or replace cables or printed circuit boards when the Instrument power is on. Electrical transients created by connecting or disconnecting cables and printed circuit boards with power applied can severely damage the Instrument components. Always switch off the AC power before disconnecting or connecting any components or cables.

1.8 Operational Precautions, Limitations, and Hazards

The following operational precautions, limitations, and hazard warnings are provided:

- 1. Barcode labels on specimen tubes must be facing outwards when in Sample Racks.
- 2. Do not use specimen tubes larger than 100 mm in height or smaller than 12 mm in diameter.
- 3. Do not use any Bead Pack or Reagent Wedge if the barcode label has been damaged or removed.
- 4. Use only IMMULITE 2000 System Reagents with the IMMULITE 2000 Analyzer.
- 5. Use only IMMULITE 2500 System Reagents with the IMMULITE 2500 Analyzer.
- **6.** Do not reuse IMMULITE 2000/2500 Reagent Wedges.
- 7. Read and carefully follow the package inserts supplied with each IMMULITE 2000/2500 Kit before using.
- **8.** It is very important that alkaline phosphatase-free water be used in the water reservoir. The chemiluminescent substrate used in the IMMULITE 2000/2500 Analyzer is exquisitely sensitive to alkaline phosphatase and high non-specific background counts may result if impure water is used.
- 9. Use only the specially designed IMMULITE 2000/2500 Analyzer Reaction Tubes on the Analyzer.
- **10.** The Bead Carousel requires six hours to equilibrate the dehumidification chamber to <20% RH when power to the Instrument has been turned off. No error messages about bead carousel humidity levels are displayed at this time. Each Bead Pack is sealed with desiccant inside and is valid for use.
- **11.** The polypropylene Dilution Well insert must be installed before performing dilutions or the well will be damaged.
- 12. Do not block the fan vents on the sides and back panel of the Instrument.
- 13. The Instrument must be connected to a dedicated 220V power service.
- **14.** When priming the substrate and trigger nozzles, dispense directly into the Reagent Pipettor Drain. Do not direct nozzle flow against the Reagent Pipettor probe.

Chapter 2: Installation

2.1 Requirements

The following are location requirements to follow for a successful IMMULITE 2000/2500 Analyzer installation.

<u>Note:</u> If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. Refer to **Appendix F** in the Operator's Manual for the full warranty statement.

Electrical

The following are electrical requirements for the IMMULITE 2000/2500 Analyzer:

- The use of a dedicated 220V service is required.
- Do not install the IMMULITE 2000/2500 near centrifuges or near ultrasound, X-ray, or NMR equipment (or other sources of magnetic fields).
- The system is for use with equipment, which has no live parts, which are accessible.
- External circuits and the wiring to them should have a minimum insulation rating of 125 volts.
- The equipment that is connected to the IMMULITE 2000/2500 shall be in compliance with the appropriate IEC standard.

Space

The IMMULITE 2000/2500 Analyzer has the following space requirements:

- The IMMULITE 2000/2500 must be located on a level floor.
- The instrument requires at least 4" (10 cm) of space around the sides and back for proper airflow.

Environment

The following are environmental requirements for the IMMULITE 2000/2500 Analyzer:

- The environmental temperature should be between 18°C and 32°C.
- The relative humidity should be less than 80%.

2.2 Unpacking

Remove from the shipping cartons the IMMULITE 2000/2500 Analyzer and associated equipment and examine each piece for damage.

The shipment should consist of the following:

IMMULITE 2000/2500 instrument, including

- o 1 power cord
- 2 pipettor probe assemblies
- o 1 dilution well insert
- o 1 sample rack set (with 6 racks)
- o Substrate (Brown, 250 mL)
- Probe wash (2 L) with quick disconnect cap
- Water (6 L) with quick disconnect cap
- Liquid waste (6 L) with quick disconnect cap
- Solid Waste
- o 2 in-line filters (25 micron)
- o 1 IMMULITE 2000/2500 Operator's Manual
- o IMMULITE 2000/2500 Software CD Package (eight CD-ROMs), supplied in a suitable package:
 - User interface and control software
 - Tutorial software Supplementary, language-specific tutorial CD-ROMs (one for each of five different languages,
 - appropriate to the customer's native language)
 - Diagnostic software
 - Configuration files
 - Windows NT
 - Drivers for peripherals (printer, touchscreen, trackball, etc.)
- Customer tool kit (containing 5/16" fluidics fitting wrench, 9/64" and 3/32" Allen keys, Phillips/flathead screwdriver, scissors)
- Starter Accessory Kit (including 1 bag of 1,000 reaction tubes, 1 package of 10 solid waste Biohazard bags, and 1 package of printer paper)
- Installation Kit
 - IMMULITE 2000/2500 Installation Notes
 - Monitor Support Arm, bracket, and keyboard drawer
 - 17" touchscreen monitor with serial cable, communication cable, and power cable
 - printer with communication cable, power cord, and ink cartridge
 - keyboard
 - trackball
 - 2D laser barcode scanner

2.3 Installation Instructions

When installing the IMMULITE 2000/2500 Analyzer, follow these steps:

Note: Only authorized DPC Service Personnel should do the following.

<u>Uncrate the Instrument</u> - An area of 15 ft X 5 ft (4.5 m X 1.5 m) is required to accommodate the shipping platform, ramps, and instrument.

<u>Note</u>: Note orientation of shipping platform. Ramps will attach to only one side of platform.

- 1. Remove top cover of carton and lift sleeve straight upwards over instrument.
- **2.** Remove protective foam packaging.
- 3. Lower leveling feet approximately ½ inch (12mm) with 9/16 inch Open End Wrench.
- **4.** Remove four corner support brackets with 9/16 inch Socket Wrench.
- **5.** Raise four leveling feet to highest position.

<u>Note</u>: Feet must be at highest position to avoid contact with ground when rolling instrument down ramps.

6. Remove support blocks from bottom front and back with 9/16 inch socket wrench.

<u>Note</u>: Lifting instrument with pry bar is required to remove blocks. When lifting front of instrument, front access door must be opened to avoid damage to panel.

- 7. Attach ramps to shipping platform.
- **8. Slowly**, roll instrument down ramps.

<u>Note</u>: A minimum of two persons is required to roll instrument down platform ramps. Instrument should be pushed and handled by edges of side panels to avoid damage to covers. Proper precautions must be taken to support instrument during movement.

Install Flat Screen Monitor Arm

- **1.** Open Top Cover, by accessing manual cover release inside front panel access door.
- 2. Open right side panel by releasing fastener screw on the component deck.
- **3.** Install the new monitor arm assembly. In a small plastic bag you will find a large brass (gold color) spacer. Center this over the hole on the new monitor arm support. Place the silver portion of new monitor arm assembly into the hole.
- **4.** At the other end of the new monitor arm, insert the 20.3 cm (8 inch) metal tube so the black portion is at the top and the set screw pointing to the back.
- **5.** Attach the black monitor mounting assembly to the back of the new flat screen monitor with the four screws provided with the monitor.
- **6.** Install the monitor onto the monitor arm by placing the silver metal stud into the hole in the top of the 20.3 cm (8 inch) metal tube.
- 7. Install the new trackball and keyboard tray by fitting the hole in the back up onto the black metal stud. Install hex head screw from bottom of tray and then tighten the hex set screw on the back of the tray. The hex tools are provided with the monitor arm parts box.
- **8.** Install the hand held scanner support to the bottom of the keyboard tray using the four 6/32 nuts and locking washers. There are welded studs on either side of the tray so you can mount the scanner on the side you like.
- **9.** Mount the hand held barcode scanner on the monitor arm support with the hardware supplied.
- **10.** Place the two pieces of foam on the top of the keyboard tray. Place one piece to the left side of the track ball and the other at the back of the track ball to keep it from sliding away from the operator.

Install Cables and Printer

- **1.** Attach extension cables for video, speakers, touch screen, laser scanner, keyboard, and pointer.
- **2.** Route all cables (except the scanner cable) through the monitor arm channel to the I/O panel.
- **3.** Install spiral wrap on exposed cables and fasten the excess spiral wrapped cable with a plastic wire tie, to the plastic mounting bracket on the back of chassis, to prevent stress at connectors.
- **4.** Install the Printer to printer shelf, located inside the front left door panel. Connect power and interface cables to printer. Add paper to printer paper deck.

Figure 4 IMMULITE 2000/2500 I/O panel



Inspection of System Computers

- 1. Remove right rear panel to access system computers.
- **2.** Remove PCB support foam packing.
- **3.** Press firmly on all expansion PCBs to insure proper seating.

<u>Note</u>: ISA and PCI cards may have loosened during shipment. It is critical that these PCBs are properly seated **before** power on of the instrument.

4. Inspect all cabling to insure firm connection.

<u>Configuration for Input Power</u> - Instrument is pre-configured for an input voltage of 230 volts AC, 50/60 Hz. If the input voltage is less than 230 volts AC, re-configuration of the Isolation Transformer may be required.

Note: Instruments to Japan are pre-configured to 200 volts AC, 50/60 Hz.

1. The pre-configured voltage at the Isolation Transformer should be set to match the measured AC voltage at the wall outlet. If re-configuration is necessary, remove the left rear panel to access the Isolation Transformer. Configuration information is displayed on the transformer data plate, located on the top of the transformer assembly. Configure transformer jumpers in accordance with input voltage to achieve output voltage of 115 volts AC, +/- 5%.

<u>Note</u>: Be sure input power is disconnected from instrument when reconfiguring transformer.

<u>Power On</u> - Remove all shipping tape and packaging material prior to power on.

- 1. Connect instrument to power source and power on by toggling Main Power Switch, located inside the front left door.
- **2.** Allow instrument to reach proper operating temperature. Instrument requires approximately two hours to reach and stabilize at operating temperatures.

<u>Testing the Water</u> - The instrument must be at proper operating temperature prior to starting the water test. The use of steam distilled water is recommended.

- 1. Add Substrate to the Substrate Reservoir bottle, and prime the Substrate Solenoid Pump, lines and probe.
- 2. Run the diagnostic program WATERTEST.
- **3.** The instrument will prompt when to add two Reaction Tubes to the Tube Hopper Chain at the tube Processor Shuttle position. One of the tubes must contain 10 uL of water from the customer's water supply source; the other tube is to be empty.

Note: No beads are used for this test.

- **4.** At the completion of this test, the system will print the results of the PMT readings. The PMT open CPS reading must be multiplied by the PMT Multiplier (CPS * PMT). Result must be < 1250.
- 5. If the result is below 200 CPS, insufficient substrate was dispensed, the substrate is "dead," or the Luminometer is not at operating temperature. If the result of the substrate cup is > 1250 CPS, the substrate, reaction tube, or solenoid pump may be contaminated. In either case, repeat the water test procedure to insure the results are accurate.
- **6.** If the difference between the two results is greater than 200 CPS, contamination of the water source may be suspected. Ensure equal amounts of substrate was dispensed into the two reaction tubes, insufficient substrate dispense may also be the cause. Repeat the water test procedure to insure the results are accurate. If the repeat test produces similar results, water source contamination is the most likely cause. Repeat the water test procedure using an alternate water source.

<u>Testing The Instrument</u> – During the test run, complete the Operational Inspection section of the DPC IMMULITE Initial Inspection Form.

1. Choose RUN IMMULITE.

- **2.** Thoroughly rinse the water and probe wash containers with the same water source that successfully passed the water test.
- **3.** Fill the water and probe wash container with their respective fluids and install the supplied water and probe wash filters. Fill the substrate bottle with the supplied substrate. Prime the instrument thoroughly (20 to 25 times), including the water probe and substrate probe lines.
- **4.** Reconstitute the controls and adjustors supplied in the installation kit using the water source that has successfully passed the aforementioned water test. Also insure the reconstituted materials are allowed enough time to fully enter solution before use. Generally this is one hour, but check the package inserts to be sure.
- **5.** Run 20 replicates of TsH Low Adjustor or TsH Diluent if it is available.
- **6.** Insure that the results, in this case the raw CPS counts, of the 20 TsH replicates have a %CV less than 7%. Review the raw CPS counts and insure that no count is greater than 20% of the mean of the raw CPS counts. If any one count is, there may be a contamination issue; which will need to be addressed.
- 7. After the 20 replicates have gone through the incubator for its final incubation (i.e., the second time around) in step 5, begin to run adjustment(s) of the kit(s) supplied in the installation kit.
- **8.** Run 10 replicates of each control supplied in the installation kit as "unknowns" (do not identify as controls since no control information is entered).
- **9.** Insure the adjustment slopes are between 0.8 and 1.3. If the slopes are not within this range, call DPC Technical Services.
- **10.** Insure the absolute value of adjustment intercepts are less than or equal to the result of the following calculation. If the intercept is greater that the number calculated, call DPC Cirrus Technical Services.

Low adjustor CPS of the Master Curve X 30%

<u>Note</u>: The low adjustor CPS refers to the "Adjustor CPS" information found on the kit screen or adjustment printout (not to the CPS measured on the instrument.

11. Insure the controls are within the range noted on the package insert supplied with them in the installation kit. If they are not within range, call DPC Cirrus Technical Services.

Chapter 3: Theory of Operation

3.1 Introduction

The IMMULITE 2000/2500 System is a random-access immunoassay Analyzer, built around a proprietary means of efficiently and rapidly washing the bead solid phase. The 0.25- inch polystyrene bead is captured in a Reaction Tube that serves as the vessel for all incubations, washes, and signal development. After incubation of the sample with alkaline phosphatase-labeled reagent, rapid separation and efficient washing of the bead and Reaction Tube are achieved by high-speed spinning of the Reaction Tube on its vertical axis. The fluid contents are completely transferred to the coaxial sump chamber component of the Wash Station. Four washes are accomplished within seconds, allowing uniform, sequential processing of the Reaction Tubes and leaving the bead with no residual unbound label. The bound label is then quantified, using either the dioxetane substrate or trigger reagent to produce light. Light emission from the chemiluminescent substrate, reacting with the bound label, is proportional to the amount of analyte present in the sample.

3.2 Overview of Test Process

The operator interface is very simple. Up to 90 barcoded primary and secondary tubes, containing patient specimens, controls, adjusters, or diluents, are loaded into the Sample Racks. A maximum of 24 barcoded, assay-specific Reagent Wedges and Bead Packs are manually loaded into their respective refrigerated or dehumidified Carousels. After a Worklist is entered, the IMMULITE 2000/2500 automatically begins testing. This involves dropping a single assay-specific bead into a Reaction Tube, pipetting both the sample and the labeled, assay-specific reagent onto the bead, and transferring the Reaction Tube into the Incubator portion of the Tube Processor. The Reaction Tube is continuously agitated at 37°C for periods ranging from 30 to 180 minutes, depending on the assay. When the incubation period is completed, the tube is washed, substrate (or trigger) is added, and the amount of light generated is measured by the photomultiplier tube (PMT). Automatic attenuation of the light signal increases the dynamic range of the PMT one-hundred fold, thereby enabling accurate measurements at both extremely high and extremely low analyte concentrations.

3.3 Internal Calculations

This section provides a step-by-step description of the internal calculations performed by the IMMULITE 2000/2500 System when determining test results.

- 1. Since the IMMULITE 2000/2500's ultra-sensitive assays can produce up to several hundred million counts per second (cps), the IMMULITE 2000/2500 uses an attenuator disk in front of the photomultiplier tube (PMT) to provide accurate readings over a very broad range of light signals. This attenuator disk has three positions:
 - o *closed* completely blocks the PMT
 - o attenuated positions a neutral density filter in front of the PMT
 - o open an unfiltered position

The IMMULITE 2000/2500's attenuation filter restricts the number of photons entering the PMT, ensuring an accurate count, even if the actual cps are so high that they exceed the PMT's linear range.

- 2. For each sample, the IMMULITE 2000/2500 takes a one-second reading (dark count) in the closed position and a one-second reading (decision count) in the attenuated position.
 - If the one-second attenuated reading is less than 1,000 cps, the attenuator disk moves to the open position; otherwise, the attenuator disk remains in the attenuated position while the readings are taken.
- **3.** The IMMULITE 2000/2500 takes five one-second readings and returns the attenuator disk to the closed position.
- **4.** Dark counts are calculated by averaging the last 10 reads. This average is subtracted from each of the five readings.

Note: A dark count measurement is taken only when a Reaction Tube is in the read position.

- **5.** If the counts were measured attenuated, the mean of the five individual readings is multiplied by the instrument-specific attenuation factor to yield the total unattenuated counts per second (cps).
 - cps(unattenuated) = cps(attenuated) x attenuation factor
- **6.** To determine analyte concentrations, the IMMULITE 2000/2500 software refers to lot-specific master curve parameters which were entered into the system via the 2-D kit barcode.

3.4 The Chemiluminescent Reaction

This section provides a brief overview of the chemiluminescent reaction used in the IMMULITE 2000/2500 system.

First, the alkaline phosphatase conjugate (reagent) is bound to the bead (within the Reaction Tube) during the immunological reaction. The amount of alkaline phosphatase captured is proportional (for a sandwich assay), or inversely proportional (for a competitive assay) to the concentration of the analyte in the patient sample.

For the IMMULITE 2000:

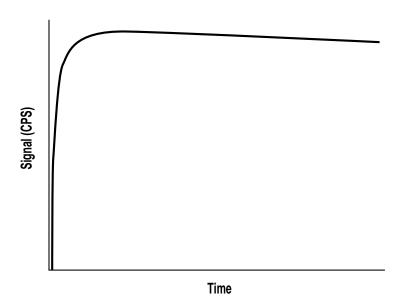
Once the Reaction Tube is washed, a luminogenic substrate is added to the Reaction Tube and it is moved onto the Luminometer chain.

For the IMMULITE 2500:

Once the Reaction Tube is washed, a luminogenic substrate is added to the Reaction Tube and it is moved onto the Luminometer Belt.

Five minutes later, the Reaction Tube arrives in front of the photomultiplier tube (PMT), where the light generated by the luminogenic reaction is measured. Unlike chemiluminescent reactions involving acridinium esters (which produce a flash of light) the enzyme-amplified reaction in the IMMULITE 2000/2500 System produces a prolonged glow, as indicated in Figure 5.

Figure 5 IMMULITE 2000/2500 Enzyme-Amplified Luminescence



In the luminogenic reaction (Figure 6 on page 3-4), the substrate (an adamantyl dioxetane phosphate¹) is dephosphorylated into an unstable anion intermediate by the alkaline phosphatase conjugate captured on the bead. The unstable intermediate emits a photon upon decomposition. The amount of light emitted is directly proportional to the amount of bound alkaline phosphatase.

Compared to other means of detection, chemiluminescence provides the highest degree of sensitivity available. In many cases, the sensitivity is orders of magnitude higher than that attainable with radioimmunoassays.

¹*LUMIGEN® PPD: 4-methoxy-4-(3-phosphatephenyl)-spiro-(1,2-dioxetane-3,2'-adamantane). LUMIGEN® is a registered trademark of LUMIGEN, Inc., Southfield, MI.

Figure 6 The IMMULITE 2000/2500 Chemiluminescent Substrate

3.5 Primary Modules

3.5.1 Introduction

Primary Modules are defined as those modules that include stepper motors and require configuration parameters and adjustments. Primary Modules require alignment through configuration (see Section 9). *Secondary Modules* (discussed in Section 3.6: Secondary Modules) are defined as those modules that require mechanical or electrical adjustments.

The Primary Modules of the IMMULITE 2000/2500 are as follows:

- Bead Carousel and Dispenser
- Dual Pipettor
- o Reagent Carousel
- Sample Carousel
- Tube Feeder
- Reaction Tube Processor
- o Dual Resolution Diluter (DRD)

Each of these modules is described in detail on the following paragraphs.

3.5.2 Bead Carousel and Dispenser Module

Description

The Bead Carousel

- provides physical support and transport of 24 individual Bead Packs, each capable of holding 200 beads. Vertically-oriented barcodes on all Bead Packs are accessible for reading by a dedicated CCD Barcode Reader.
- is housed within a dehumidified chamber maintained at <20% relative humidity. Beads can be stored on board for up to one month.
- can rotate 360° degrees in any direction for barcode identification. Beads are dispensed from any Pack one at a time, as needed.

Each Bead Pack

- o is positively identified with a barcode label
- o contains a desiccant pack which protects its contents from humidity
- o contains 200 beads
- o is a single-use, disposable component supplied with each kit

Functions

The Bead Carousel performs the following functions:

- o stores the 24 barcoded Bead Packs on board, at low humidity
- facilitates bead PAK barcode reading
- o positions selected Bead Packs at the bead-dispensing position
- o dispenses a single bead from a selected Bead Pack into a reaction tube
- o protects beads from damage by ambient humidity

Functional Components

The Bead Carousel and Dispenser module consists of the following major functional components:

- Bead carousel tray
- Bead carousel housing and drive system
- Bead carousel dehumidification system
- o Bead Pack barcode reader
- Bead dispenser mechanism

Actuators and Actuator Sensors

The module has the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Bead Carousel Indexer	Stepper motor	Quadrature	Device home sensor
Bead Dispenser	Stepper motor	None	Home and position sensors

In addition, the module includes two miscellaneous sensors:

- o bead door interlock
- o humidity detector

The module also includes two miscellaneous devices:

- Bead Carousel dehumidifier
- Bead Pack barcode reader

Design Requirements

The Bead Carousel module conforms to the following design requirements:

- The module supports a carousel having positions for 24 wedge-shaped Bead Packs.
- The carousel cannot be removed from the instrument by users.
- The operator can change individual Bead Packs at any time during instrument operation.
- Rotation of the carousel provides random access to any Bead Pack on board.
- The module is dehumidified at ≤20% relative humidity in order to provide for one-month on-board bead stability.
- The module enables the user to identify barcoded Bead Packs through the use of a dedicated barcode reader. (Bead Pack labels must be of medium or high density.)
- o The module includes an actuator that causes Bead Packs to dispense beads into reaction tubes.

Feedback Requirements

The following sensors are provided to fulfill the feedback requirements for the Bead Carousel and Dispenser (see also **Actuators and Actuator Sensors**, above):

- An *optical encoder*, which provides quadrature output and can detect half steps on a 0.9° stepper.
- A *home sensor* (not coincident with normally-used device positions) is provided on all stepper-driven devices for purposes of absolute device-positioning information.
- An appropriate sensor is used to detect the status of the Bead Carousel housing lid.
 - When the Bead Carousel door is *open*, front-end pipetting operations are suspended.

- When the Bead Carousel door is *closed*, Bead Pack barcodes are interrogated and pipetting resumes.
- A *hygristor* provides feedback on the bead housing humidity.

Error-Correction Requirements

The Bead Carousel and Dispenser module has the following error-detection capabilities:

- o Detection and correction of Bead Carousel jams without causing mechanical damage
- Detection and correction of Bead Pack actuation failures without causing mechanical damage
- Detection of housing humidity exceeding 20% RH and advising users of such a problem

3.5.3 Dual Pipettor Module Assistance

Description

The Dual Pipettor module consists of two arms that are specific to either sample or reagent.

tubes or to the dilution well, along with an appropriate amount of diluent.

- O The *sample arm* rotates and translates the *Sample Probe* among various positions on the Sample Carousel, Sample Probe Wash Station, Dilution Well, and Reaction Tube Processor.

 The sample arm picks up specimens contained in primary and secondary sample tubes from their positions on the Sample Carousel. These specimens may then be delivered directly either to reaction
- The *reagent arm* rotates and translates the *Reagent Probe* among various positions on the Reagent Carousel, Reagent Probe Wash Station, and Reaction Tube Processor.
 - The reagent arm allows pick-up of reagents from any compartment of any Reagent Wedge on the Reagent Carousel. These reagents are delivered directly to reaction tubes for either test processing or sample pretreatment.

Both pipetting arms

- Can simultaneously actuate their probes both vertically and horizontally
- Can access as many as three different fluid containers within a single 18-second cycle
- Operate independently of one another
- Have the following capabilities:
 - capacitative level sensing
 - tip jam detection

Functions

The Dual Pipettor module performs the following functions to facilitate the distribution of fluids:

- positions the sample probe at various locations
- positions the reagent probe at various locations

Functional Components

The Dual Pipettor module consists of the following major functional components:

Component	Description
Sample arm	An articulated arm which simultaneously actuates the Sample probe both vertically and rotationally.
Sample probe	This probe has access to the Sample Carousel, Probe Wash Station, Dilution Well, and the pipetting position.
Reagent arm	An articulated arm, which simultaneously actuates an arm probe, both vertically and rotationally.
Reagent probe	This probe has access to the Reagent Carousel, a Wash Station, and the Reaction Tube Pipetting Station.

Access Points

The Dual Pipettors have the following access points:

- Sample Arm
 - Sample Carousel inner tube row
 - Sample Carousel outer tube row
 - Sample Probe wash station drain
 - Sample Probe wash station blind hole
 - Dilution well
 - Tube Processor pipettor station
- Reagent arm
 - Reagent Wedge inner (C) compartment
 - Reagent Wedge middle (B) compartment
 - Reagent Wedge outer (A) compartment
 - Allergy Wedge Vile 1
 - Allergy Wedge Vile 2
 - Allergy Wedge Vile 3
 - Allergy Wedge Vile 4
 - Allergy Wedge Vile 5
 - Allergy Wedge Vile 6
 - Reagent Probe wash station drain
 - Reagent Probe wash station blind hole
 - Tube processor pipetting station IMMULITE 2000 ONLY
 - Incubator 1 pipetting station IMMULITE 2500 ONLY
 - Incubator 2 pipetting station IMMULITE 2500 ONLY

Actuators and Actuator Sensors

The Dual Pipettors have the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Sample Arm X rotation	Stepper motor	Quadrature	Device home sensor

Actuator Name	Actuator Type	Optoencoder	Other feedback
Sample Arm Z motion	Stepper motor	Quadrature	Device home sensor
Reagent Arm X rotation	Stepper motor	Quadrature	Device home sensor
Reagent Arm Z motion	Stepper motor	Quadrature	Device home sensor

In addition, the module includes four miscellaneous sensors:

- sample arm tip jam sensor
- o sample level sensor
- reagent arm tip jam sensor
- o reagent level sensor

Design Requirements

The Dual Pipettor module conforms to the following design requirements:

- Probe arms
 - provide precision, accuracy, and reliability of motion
 - provide access to locations outlined in **Access Points**, above.
- The probes
 - provide for sampling from the bottom of all supported tube sizes
 - provide reliable level sensing
 - are readily customer-replaceable

Feedback Requirements

The following sensors are provided to fulfill the feedback requirements for the Dual Pipettor module (see also **Actuators and Actuator Sensors**, above):

- An *optical encoder* provides quadrature output for all motion axes of both arms for purposes of error detection.
- The *vertical axis encoders* permit detection of foreign objects (such as human hands) beneath the probes. This provides an added measure of user safety by preventing accidental puncture wounds. In conjunction with the encoders, *home sensors* provide absolute positioning information.
- *Tip jam sensors*, for both vertical motion axes, provide redundant information that can be used to ensure that puncture wounds cannot occur.
- Level sensors for each probe are used to detect reagent and sample levels.

Error-Correction Requirements

The Dual Pipettor module has the following error-correction capabilities:

- Detection and correction of rotation errors without causing either mechanical damage or user injury.
- Detection of vertical motion errors, such as those caused by probe impact with human appendages, without causing physical damage. In such cases, the motion is stopped before force sufficient to cause injury is exerted.

3.5.4 Reagent Carousel Module

Description

The Reagent Carousel

- provides physical support and movement of 24 individual Reagent Wedges.
- o includes a closed, refrigerated chamber which permits on-board reagent storage for up to one month
- o can rotate 360° in any direction for the following purposes:
 - to position Reagent Wedges for reading barcodes. (The sample barcode reader doubles as a reader for Reagent Wedge barcodes.)
 - to position the Wedges for pipetting.

Each Reagent Wedge

- o is composed of three compartments, each of which contains sufficient volume for 200 tests
- can be removed individually from the carousel or, alternatively, the entire carousel tray can be lifted out of the module

Functions

The Reagent Carousel module and associated Reagent Wedges perform the following functions:

- retains 24 barcoded Reagent Wedges on board at 4°-8°C
- o facilitates Reagent Wedge barcode reading
- positions selected Reagent Wedges at appropriate sampling positions
- o protects liquid reagents from environmentally-induced damage

Functional Components

The Reagent Carousel module consists of the following functional components:

- o Reagent tray
- o Reagent housing and drive system
- Reagent refrigeration system

Actuators and Actuator Sensors

The Reagent Carousel has the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Reagent Carousel indexer	Stepper motor	Quadrature	Device home sensor
Reagent Wedge lid opener	Stepper motor	None	Home and Alternate sensors

In addition, the module includes five miscellaneous sensors/devices:

- small reagent door open
- o large reagent door open
- o reagent housing temperature sensor
- o reagent barcode window defroster
- 2 thermoelectric coolers

Design Requirements

The Reagent Carousel conforms to the following design requirements:

- The module supports a carousel, having positions for 24 wedge-shaped Reagent Wedges.
- The carousel is removable from the instrument by users.
- One Reagent Wedge at a time can be removed without rotating the Reagent Carousel during instrument operation. Pipetting operations can be suspended to gain such access.
- Tray rotation provides for random access to any Reagent Wedges on board.
- The module is refrigerated at between 4 and 8°C to provide on-board reagent stability for one month.
- The module facilitates barcoded Reagent Wedge identification through use of the sample barcode reader.
- The module ensures barcode readability by preventing fog formation on the reagent barcode view port under conditions of condensation.
- The Reagent Wedge lid opener opens and closes each Reagent Wedge lid for each reagent when required.

Feedback Requirements

The following sensors are provided to fulfill the feedback requirements for the Reagent Carousel module (see also **Actuators and Actuator Sensors**):

- An *optical encoder* provides quadrature output and can detect half steps on a 0.9° stepper motor.
- A *home sensor* (not coincident with normally-used device positions) is provided on all devices for absolute device-positioning information.
- An appropriate sensor is used to detect the status of the reagent door.
 - When the door is *open*, front-end pipetting operations are suspended.
 - When the door is *closed*, reagent barcodes are read and pipetting resumes.
- A *thermistor* provides feedback on reagent housing temperatures.

Error-correction Requirements

The Reagent Carousel module has the following error-detection capabilities:

- o Detection and correction of Reagent Carousel jams without causing mechanical damage
- o Detection and correction of Reagent Wedge lid-opening failures without causing mechanical damage
- Detection of housing temperatures exceeding 8°C (which is indicative of TED failure) and advising users of the problem

3.5.5 Sample Carousel Module

Description

The Sample Carousel provides support and movement of six easily-removable racks. Each rack is capable of holding 15 Specimen or Diluent Tubes, thus providing an on-board capacity of 90 tubes.

These tubes

- can be of any of the following *sizes*:
 - 12 x 75mm
 - 13 x 75mm
 - 12 x 100mm
 - 13 x 100mm
 - 16 x 100mm
 - 10 x 50mm (microsample)
- may be either of two *types*:
 - primary (gel separator) tubes
 - secondary (pour-off) tubes

The Sample Carousel can rotate 360° in any direction to identify barcodes and to position specimens for pipetting. The barcode reader supports a variety of barcode formats and can read both specimen and Reagent Wedge barcodes. The user can replace racks of specimen tubes easily at any time.

Functions

The Sample Carousel performs the following functions:

- retains 90 specimen tubes on board in six removable racks
- reads specimen tube barcodes
- o positions selected specimens at the *sampling position*
- o identifies specimen tube heights

Functional Components

The module consists of the following major components:

- Sample Carousel and drive system
- Sample racks
- Sample barcode reader

Actuators and Actuator Sensors

The module has the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Sample Carousel indexer	Stepper motor	Quadrature	Device home sensor

In addition, the module includes four miscellaneous sensors:

- o 2 inner row tube detectors—heights: 75mm and 100mm
- 2 outer row tube detectors—heights: 75mm and 100mm

Design Requirements

The Sample Carousel module conforms to the following design requirements:

The Carousel must

- support six sample racks which are easily removed and replaced
- provide for level sensing of samples
- be easily rotated manually in both directions
- o accurately position specimen tubes for barcode reading and pipetting
- o include clearly-visible, capital letters A through F (or number 1 through 6) to denote rack positions

Feedback Requirements

The following sensors are provided to fulfill the feedback requirements for the Sample Carousel module (see also **Actuators and Actuator Sensors**):

- All *optical encoders* provide quadrature output and can detect half steps on a 0.9° stepper motor. These sensors provide feedback on all stepper axes.
- A *home sensor* (not coincident with normally-used device positions) is provided on all devices for absolute device-positioning information.
- o Optosensors are used
 - to detect the presence of unbarcoded tubes in the sample racks
 - to distinguish tubes of differing heights (75mm or 100mm)

Error-Correction Requirements

The Sample Carousel module has the capability of detecting and correcting carousel jams without causing mechanical damage.

3.5.6 Tube Feeder Module

Description

The Tube Feeder module is a device that accepts reaction tubes in bulk, orients them, and delivers them to the pipetting station in the Tube Transporter.

Functions

The Tube Feeder module performs the following functions:

- o accepts new reaction tubes from the user
- stores new reaction tubes on board
- o positions reaction tubes to receive a bead from the Bead Carousel
- o transports reaction tubes to the pipetting position of the Tube Processor module

Functional Components

The module consist of the following major functional components:

- o Reaction tube feeder
 - Reaction tube hopper
 - Reaction tube hopper elevator
 - Reaction tube orientation ramp and queue
- o Reaction tube loader
 - Rotary tube indexer
 - Transport chain
 - Processor shuttle

Actuators and Actuator Sensors

The module has the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Hopper elevator	AC induction	None	Flag to detect motion
Tube indexer	Stepper motor	Quadrature	Device home sensor
Tube transport chain	Stepper motor	Quadrature	Device home sensor
Processor shuttle	Stepper motor	Quadrature	Device home sensor

In addition, the module includes six miscellaneous sensors:

- o reaction tube detector in queue empty
- o reaction tube detector in queue full
- reaction tube detector at tube indexer
- 1.2 bead-in-tube detectors
 - 1 positioned to detect a single bead within a tube
 - 1 positioned to detect a second bead within a tube
- tube feeder interlock

Design Requirements

The Tube Feeder module conforms to the following design requirements:

- The user must have easy access to the following areas:
 - Tube hopper and elevator (for purposes of filling, cleaning, and removal of foreign objects)
 - Tube orientation ramp
 - Tube indexer disk
- The Tube Feeder must not
 - cause noticeable scratching of reaction tube surfaces
 - generate noticeable quantities of dust through grinding of tubes
 - generate static charge sufficient to cause dust accumulation
- Noise output should not exceed 70 dB at one foot from the hopper when the instrument cabinet doors are open.

Feedback Requirements

The following sensors are provided to fulfill the feedback requirements for the Tube Feeder module (see also **Actuators and Actuator Sensors**, above):

- Optical encoders produce quadrature output, providing feedback on all stepper axes.
- *Home sensors* (not coincident with normally-used device positions) are provided on all stepper-driven devices to provide absolute device-positioning information.
- The tube hopper assembly includes a single sensor to verify that the elevator is moving
- Reaction tube detectors are located at the top (10 tubes) and bottom (3 tubes) positions of the tube queue. These detectors are used to determine when the tube elevator should be activated.
- A *reaction tube detector* is also located at the tube queue position on the tube indexer. This detector is used to ensure that beads are dispensed only when tubes are present to receive them.
- A *tube feeder interlock sensor* is used to suspend tube-feeding operations when the user opens the hopper/elevator assembly.

Error-Correction Requirements

The Tube Feeder module has the following error-correction capabilities:

- Detection of elevator stalls, deactivation of the device, and informing the user of the problem.
- Detection and correction of stalls of the tube indexer, load chain, or tube processor shuttle without causing mechanical damage.
- Detection and correction of situations where an incorrect number of beads is found in a reaction tube. If, following an attempt to dispense, no beads are found, a second attempt is made. Conversely, if two beads are present in one tube, the tube is disposed.
- Detection of the absence of a reaction tube at the tube queue position on the tube indexer, thus aborting bead dispensing.

3.5.7 Reaction Tube Processor Modules

<u>IMMULITE 2000:</u>

Description

The Reaction Tube Processor is the module in which reaction tube incubation, mixing, washing, and luminometry are performed.

- The *transfer* and *incubator chains* transport reaction tubes along a serpentine path from the pipetting station to the wash station.
- The *luminometer chain* transports reaction tubes from the wash station to the read station and then to the tube exit.
- All chains pass through a housing maintained at $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$. A reaction tube shaker within this housing provides for continuous agitation of tubes on the incubator chain and the luminometer chain.
- Temperature control is provided by means of a circuit that
 - utilizes output from thermistors mounted on the blocks
 - powers incubator and luminometer block heaters.
- The *reaction tube wash station* washes tubes via axial centrifugation. This wash station consists of an angled, splined gear, surrounded by a sump receptacle and a tube lifter.
 - First, tubes are lifted into the wash station. They are spun five times. The first spin removes the sample and reagent mixture. 400µl of water is dispensed prior to the second, third, fourth, and fifth spins.
 - Then, when rotation ceases, tubes are dropped down before they are pushed onto the Luminometer Chain by the Luminometer shuttle. 200µl of substrate is dispensed into each tube as it passes underneath the substrate probe.
- Tubes are carried along the Luminometer Chain to the *read station*. This station employs a photomultiplier tube (PMT) to take light-emission measurements on Reaction Tubes as they pass.
- A *shutter* is employed to prevent "crosstalk" between adjacent tubes at the read station. This device physically isolates the tube at the PMT from those surrounding it.

- An attenuator disk is mounted between the PMT and the read station. This disk has three positions:
 - Dark (PMT receives no light)
 - Unattenuated (PMT receives full light output of the reaction tube)
 - Attenuated (a neutral-density filter is positioned between the PMT and reaction tube)

Functions

The Reaction Tube Processor module performs the following functions:

- accepts reaction tubes
- retains reaction tubes while sample and/or reagent are dispensed into the tubes
- incubates and agitates reaction tubes
- maintains temperature of reaction mixtures contained in the reaction tubes
- recycles reaction tubes, as necessary, for additional incubation cycles
- o separates free fractions from bound fractions of specimen via axial centrifugation of the reaction tube
- o dispenses substrate into the reaction tube
- measures photons emitted from the reaction tube
- o transports spent reaction tubes from the Luminometer to the solid waste container

During most of the above process, reaction tubes are secured within the instrument so that their contents cannot escape under typical operating conditions. When processing is completed, the spent tubes (containing spent beads and substrate) are disposed of without requiring additional handling; they present no biohazard to the operator beyond that normally associated with handling a solid waste box.

Functional Components

The Reaction Tube Processor module consists of the following major functional components:

- Incubator
 - Geneva transfer and incubator chains
 - reaction tube shaker bars
 - Luminometer shuttle
- Reaction tube wash station
 - tube lifter
 - tube wash spinner
 - wash station sump and drain
 - vacuum pump
 - water probe
- Luminometer
 - luminometer chain
 - substrate probe and heater
 - shutter
 - attenuator disk

The module has the following tube handling stations:

- pipetting station
- o immunological incubation chamber
- tube wash station

- o luminometer incubation chamber
- read station
- o tube exit

Actuators and Actuator Sensors

The module has the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Transfer/incubator chain actuator	Stepper motor	Quadrature	Device home sensor
Luminometer chain actuator	Stepper motor	Quadrature	Encoder index pulse for Home position
Luminometer shuttle	Stepper motor	Quadrature	Encoder index pulse for Home position
Shaker actuator	AC induction	None	Flag to detect motion
Tube lifter actuator	Stepper motor	Quadrature	Device home sensor
Tube spinner actuator	Brushless DC	None	Speed readout (Hall effect sensors)
Shutter actuator	Stepper motor	Quadrature	Device home sensor
Attenuator disk actuator	Stepper motor	Quadrature	Device home sensor

This module also includes seven miscellaneous sensors:

- 1 reaction tube detector
 - 1 at the pipetting station
- **o** 3 thermistors
 - Substrate Heater temperature
 - Incubator temperature
 - Luminometer temperature
- water probe-in-place detector
- substrate probe-in-place detector
- trigger probe-in-place detector

The module includes the following miscellaneous devices:

- **o** thermostat (2)
- o incubator and luminometer heaters
- o substrate heater
- photomultiplier tube (PMT)

Design Requirements - Incubator

The Incubator conforms to the following design requirements:

- o The module's casing is constructed so as to provide substantial "black body" thermal mass to help maintain the unit's temperature at $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$. Insulating materials are also used to prevent heat loss to surrounding components where appropriate.
- o Indexing of the two *tube processor chains* is a linked, sequential event, so that the transfer chain moves first, followed immediately by the incubator chain. Reaction tubes are transferred from the transfer chain to the incubator chain when the indexing process occurs.
- The *shaker* oscillates in a linear manner to provide constant agitation of reaction tubes in both the incubator and luminometer sections of the tube processor. Tubes are not agitated as they pass through turns either in serpentine sections of their path or in liquid-dispensing locations.
- The unit allows *reaction tubes* to travel indefinitely through its incubation section or to be transferred to its luminometer section.
- The transfer and incubator chains index every 18 seconds; one cycle through the unit's incubation section requires 30 minutes. Because of this requirement, there are 102 tube positions from the pipetting station to the wash station.

Design Requirements - Reaction Tube Washing Station

The Reaction Tube Washing Station conforms to the following design requirements:

- A *tube lifter* is used to elevate reaction tubes from their position on the transfer chain into the wash station. This lifter prevents any build-up of potential energy which might cause beads to fly out of reaction tubes during processing. The lifter also reliably returns tubes to the transfer chain when washing is complete.
- The tube lifter incorporates a *drain*, suitable for collecting drips from the water probe.
- A *probe* is used to inject water into reaction tubes at the wash station. This probe is easily removed by the user. The reagent pipettor wash drain allows priming of this probe.
- A *splined gear* is used to spin reaction tubes on their vertical axes. Reaction tubes are always aligned with this chuck to provide thorough washing of the tube walls.
- A *stationary sump* surrounds a portion of the reaction tube during the washing process. This sump provides for disposal of fluids *only* into the liquid waste drain system. A vacuum pump draws the waste liquid from the sump to the waste tube. No fluids are allowed to escape during or after the spin cycle.
- The washing of beads in reaction tubes is accomplished by intermittent injection of water between tube-spinning cycles. The extent of washing is assay-specific.
- Beads in reaction tubes undergo no discernible mechanical damage during the washing process.
- The tube spinner rotates at a minimum of 7,000 RPM.

Design Requirements - Luminometer

The Luminometer conforms to the following design requirements:

- o The module's casing is constructed so as to provide substantial "black body" thermal mass to help maintain the unit's temperature at $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$. Insulating materials are also used to prevent heat loss to surrounding components where appropriate.
- The module is constructed of, and protected by, materials that are not adversely affected by water, substrate, Trigger 1 or Trigger 2².
- The interior surface of the luminometer is non-reflective, flat black.
- o The luminometer chain indexes once every 18 seconds. It takes 5 minutes for a reaction tube to move from the substrate position to the read station. Because of this requirement, there are 19 tube positions from the substrate-dispensing position to the read station.
- A *substrate heater* module is located on the luminometer chain in a position immediately adjacent to the tube wash station. The user for daily cleaning integrates this device into the substrate probe so that the entire assembly is easily removable. The heater's temperature is controlled independently of the incubator and luminometer modules.
- The *read station* is protected from exterior light leakage, such that dark counts are less than 300 CPS when a flashlight is shined at the trigger probe.
- A *probe* is included at the read station to deliver Trigger reagents 1 and 2 into the reaction tube, when required. This probe is easily removable by the user for daily cleaning.
- The reagent pipettor *drain* allows priming of the trigger probe.
- A *shutter* is used to isolate reaction tubes in the read station from adjacent tubes. The trigger probe is attached to this shutter so that it moves in conjunction with the shutter.
- An *attenuator disk* is mounted between the tube in the read station and the PMT. This disk has three possible positions:
 - Dark (PMT receives no light) to measure electrical background
 - Unattenuated (PMT receives full signal produced by reaction tube)
 - Attenuated (PMT receives signal through a neutral-density filter)
- A *tube exit* is located 20 positions from the read station and allows no exterior light leakage. When a flashlight is shined at the tube exit, dark counts are less than 300 CPS.

Feedback Requirements - Incubator

The following sensors are provided to fulfill the feedback requirements for the Incubator component (see also **Actuators and Actuator Sensors**, above):

- All *optical encoders* provide quadrature output and can detect half steps on a 0.90 stepper motor. These sensors provide feedback on all stepper axes.
- A *home sensor* (not coincident with normally-used device positions) is included on stepper-driven devices to provide absolute device-positioning information.

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² Trigger 1 and Trigger 2 are currently unavailable.

- Two *thermistors* independently monitor temperatures within the incubation and luminometer sections of the unit. Both thermistors are accurate to within 0.1°C at 37°C.
- An *optosensor* detects failures of the tube shaker bar by sensing a flag on the bar.

Feedback Requirements - Reaction Tube Wash Station

The following sensors are provided to fulfill the feedback requirements for the Reaction Tube Wash Station (see also **Actuators and Actuator Sensors**, above):

- An *optical encoder* provides quadrature output for the tube lifter axis, allowing detection of errors.
- The tube lifter also has a *home sensor* (not coincident with normally-used device positions) to provide absolute device-positioning information.
- The tube spinner's *brushless DC motor-driven circuit* provides feedback on the spinner's speed as well as error-detection.
- A water probe micro switch ensures that the user has removed the probe from the unit during priming.

Feedback Requirements - Luminometer

The following sensors are provided to fulfill the feedback requirements for the Luminometer (see also **Actuators and Actuator Sensors**, above):

- All *optical encoders* provide quadrature output and can detect half steps on a 0.90 stepper motor. These sensors provide feedback on all stepper axes.
- A *substrate probe micro switch* is included to ensure that the probe has been removed from the unit during priming by the user.
- Two *thermistors* independently monitor temperatures within the incubation and luminometer sections of the unit. Both thermistors are accurate to within 0.1°C at 37°C.
- A *substrate heater module* provides information about the actual temperature.
- A *trigger probe detector* is provided to ensure that the probe has been removed from the unit during priming by the user.

Error-Correction Requirements - Incubator

The Incubator has the following error-correction capabilities:

- Detection and correction of transfer or incubator jams without causing mechanical damage.
- Detection of shaker failure.
- Detection, correction, and re-try of luminometer shuttle jams without causing mechanical damage.

Error-Correction Requirements - Reaction Tube Wash Station

The Reaction Tube Wash Station has the following error-correction capabilities:

- Detection and correction of tube lifter jams without causing mechanical damage.
- Detection of electronic failure of the tube spinner.

Error-Correction Requirements - Luminometer

The Luminometer has the following error-correction capabilities:

- Detection and correction of Luminometer chain jams without causing mechanical damage.
- Detection of substrate heater failure.
- o Detection, correction, and re-try of shutter jams without causing mechanical damage.
- o Detection, correction, and re-try of tube lifter jams without causing mechanical damage.

IMMULITE 2500:

Description

The Reaction Tube Processor is the area in which reaction tube incubation, mixing, washing, and luminometry are performed.

- The *transfer* and *incubator belts* transport reaction tubes along parallel paths from the pipetting station to the wash station.
- The *luminometer belt* transports reaction tubes from the wash stations to the read station and then to the tube exit.
- All chains pass through a housing maintained at $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$. A passive shaking method within this housing provides for continuous agitation of tubes on the incubator belt and the Luminometer Belt.
- Temperature control is provided by means of a circuit that
 - utilizes output from thermistors mounted on the blocks
 - powers incubator and luminometer block heaters.
- The *reaction tube wash stations* wash tubes via axial centrifugation. The wash stations consist of an angled, splined gear, surrounded by a sump receptacle and a tube lifter.
 - First, tubes are lifted into the wash station. They are spun five times. The first spin removes the sample and reagent mixture. 400µl of water is dispensed prior to the second, third, fourth, and fifth spins.
 - Then, when rotation ceases, tubes are dropped down before they are pushed onto the Luminometer Belt by the Wash Transfer. 200µl of substrate is dispensed into each tube as it passes underneath the substrate probe.
- Tubes are carried along the Luminometer Belt to the *read station*. This station employs a photomultiplier tube (PMT) to take light-emission measurements on Reaction Tubes as they pass.
- An attenuator disk is mounted between the PMT and the read station. This disk has three positions:
 - Dark (PMT receives no light)
 - Unattenuated (PMT receives full light output of the reaction tube)
 - Attenuated (a neutral-density filter is positioned between the PMT and reaction tube)

Functions

The Reaction Tube Processing modules performs the following functions:

- o accepts reaction tubes
- retains reaction tubes while sample and/or reagent are dispensed into the tubes
- o incubates and agitates reaction tubes
- o maintains temperature of reaction mixtures contained in the reaction tubes
- o recycles reaction tubes, as necessary, for additional incubation cycles
- o separates free fractions from bound fractions of specimen via axial centrifugation of the reaction tube
- o dispenses substrate into the reaction tube
- measures photons emitted from the reaction tube
- o transports spent reaction tubes from the Luminometer to the solid waste container

During most of the above process, reaction tubes are secured within the instrument so that their contents cannot escape under typical operating conditions. When processing is completed, the spent tubes (containing spent beads and substrate) are disposed of without requiring additional handling; they present no biohazard to the operator beyond that normally associated with handling a solid waste box.

Functional Components

The Reaction Tube Processing modules consists of the following major functional components:

- Incubator
 - 2 incubator belts
 - 2 wash transfers
 - 1 incubator belt transfer
- Reaction tube wash stations
 - tube lifter
 - tube wash spinner
 - wash station sump and drain
 - vacuum pump
 - water probe
- Luminometer
 - luminometer belt
 - substrate probe and heater
 - attenuator disk
 - luminometer disk
 - PMT transfer
 - Exit transfer

The module has the following tube handling stations:

- o pipetting station
- immunological incubation chamber
- o tube wash station
- o luminometer incubation chamber
- read station
- o tube exit

Actuators and Actuator Sensors

The module has the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Transfer/incubator chain actuator	Stepper motor	Quadrature	Device home sensor
Luminometer Belt actuator	Stepper motor	Quadrature	Device home sensor
Luminometer shuttle	Stepper motor	Quadrature	Encoder index pulse for Home position
Tube lifter actuator	Stepper motor	Quadrature	Device home sensor
Tube spinner actuator	Brushless DC	None	Speed readout (Hall effect sensors)
Attenuator disk actuator	Stepper motor	Quadrature	Device home sensor

This module also includes seven miscellaneous sensors:

- 5 reaction tube detectors
 - 1 at the pipetting station
- **o** 3 thermistors
 - Substrate Heater temperature
 - Incubator temperature
 - Luminometer temperature
- substrate probe-in-place detector

The module includes the following miscellaneous devices:

- thermostat (2)
- o incubator and luminometer heaters
- substrate heater
- photomultiplier tube (PMT)

Design Requirements - Incubator

The Incubator conforms to the following design requirements:

- o The module's casing is constructed so as to provide substantial "black body" thermal mass to help maintain the unit's temperature at $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$. Insulating materials are also used to prevent heat loss to surrounding components where appropriate.
- o Indexing of the two *tube processor chains* is a linked, sequential event, so that the transfer chain moves first, followed immediately by the incubator chain. Reaction tubes are transferred from the transfer chain to the incubator chain when the indexing process occurs.
- The unit allows *reaction tubes* to travel indefinitely through its incubation section or to be transferred to its luminometer section.
- The transfer and incubator chains index every 18 seconds; one cycle through the unit's incubation time is determined by the assay requirements. , There are 102 tube positions from the pipetting station to the wash station for processing the assays.

Design Requirements - Reaction Tube Washing Station

The Reaction Tube Washing Station conforms to the following design requirements:

- O A tube lifter is used to elevate reaction tubes from their position on the transfer chain into the wash station. This lifter prevents any build-up of potential energy which might cause beads to fly out of reaction tubes during processing. The lifter also reliably returns tubes to the transfer chain when washing is complete.
- The tube lifter incorporates a *drain*, suitable for collecting drips from the water probe.
- A *probe* is used to inject water into reaction tubes at the wash station. This probe is easily removed by the user. The reagent pipettor wash drain allows priming of this probe.
- A *splined gear* is used to spin reaction tubes on their vertical axes. Reaction tubes are always aligned with this chuck to provide thorough washing of the tube walls.
- A *stationary sump* surrounds a portion of the reaction tube during the washing process. This sump provides for disposal of fluids *only* into the liquid waste drain system. A vacuum pump draws the waste liquid from the sump to the waste tube. No fluids are allowed to escape during or after the spin cycle.
- The washing of beads in reaction tubes is accomplished by intermittent injection of water between tube-spinning cycles. The extent of washing is assay-specific.
- Beads in reaction tubes undergo no discernible mechanical damage during the washing process.
- The tube spinner rotates at a minimum of 7,000 RPM.

Design Requirements - Luminometer

The Luminometer conforms to the following design requirements:

- **o** The module's casing is constructed so as to provide substantial "black body" thermal mass to help maintain the unit's temperature at $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$. Insulating materials are also used to prevent heat loss to surrounding components where appropriate.
- The module is constructed of, and protected by, materials that are not adversely affected by water or substrate...
- The interior surface of the luminometer is non-reflective, flat black.
- The Luminometer Belt indexes once every 18 seconds. It takes 5 minutes for a reaction tube to move from the substrate position to the read station. Because of this requirement, there are only 19 tube positions used.
- A *substrate heater* module is located on the Luminometer Belt in a position immediately adjacent to the tube wash station. The user for daily cleaning integrates this device into the substrate probe so that the entire assembly is easily removable. The heater's temperature is controlled independently of the incubator and luminometer modules.
- The *read station* is protected from exterior light leakage, such that dark counts are less than 300 CPS when a flashlight is shined at the Luminometer.
- A disk is used to isolate reaction tubes in the read station from adjacent tubes.
- An *attenuator disk* is mounted between the tube in the read station and the PMT. This disk has three possible positions:
 - Dark (PMT receives no light) to measure electrical background
 - Unattenuated (PMT receives full signal produced by reaction tube)
 - Attenuated (PMT receives signal through a neutral-density filter)
- A *tube exit* is located 90° from the read station and allows no exterior light leakage. When a flashlight is shined at the tube exit, dark counts are less than 300 CPS.

Feedback Requirements - Incubator

The following sensors are provided to fulfill the feedback requirements for the Incubator component (see also **Actuators and Actuator Sensors**, above):

- All *optical encoders* provide quadrature output and can detect half steps on a 0.90 stepper motor. These sensors provide feedback on all stepper axes.
- A *home sensor* (not coincident with normally-used device positions) is included on stepper-driven devices to provide absolute device-positioning information.

• Two *thermistors* independently monitor temperatures within the incubation and luminometer sections of the unit. Both thermistors are accurate to within 0.1°C at 37°C.

Feedback Requirements - Reaction Tube Wash Stations

The following sensors are provided to fulfill the feedback requirements for the Reaction Tube Wash Station (see also **Actuators and Actuator Sensors**, above):

- An optical encoder provides quadrature output for the tube lifter axis, allowing detection of errors.
- The tube lifter also has a *home sensor* (not coincident with normally-used device positions) to provide absolute device-positioning information.
- The tube spinner's *brushless DC motor-driven circuit* provides feedback on the spinner's speed as well as error-detection.
- A water probe micro switch ensures that the user has removed the probe from the unit during priming.

Feedback Requirements - Luminometer

The following sensors are provided to fulfill the feedback requirements for the Luminometer (see also **Actuators and Actuator Sensors**, above):

- All *optical encoders* provide quadrature output and can detect half steps on a 0.90 stepper motor. These sensors provide feedback on all stepper axes.
- A *substrate probe micro switch* is included to ensure that the probe has been removed from the unit during priming by the user.
- Two *thermistors* independently monitor temperatures within the incubation and luminometer sections of the unit. Both thermistors are accurate to within 0.1°C at 37°C.
- A *substrate heater module* provides information about the actual temperature.

Error-Correction Requirements - Incubator

The Incubator has the following error-correction capabilities:

- Detection and correction of transfer or incubator jams without causing mechanical damage.
- Detection, correction, and re-try of wash station transfers and belt transfer jams without causing mechanical damage.

Error-Correction Requirements - Reaction Tube Wash Station

The Reaction Tube Wash Station has the following error-correction capabilities:

- Detection and correction of tube lifter jams without causing mechanical damage.
- Detection of electronic failure of the tube spinner.

Error-Correction Requirements - Luminometer

The Luminometer has the following error-correction capabilities:

- Detection and correction of Luminometer belt jams without causing mechanical damage.
- Detection of substrate heater failure.
- Detection, correction, and re-try of luminometer disk jams without causing mechanical damage.

Detection, correction, and re-try of tube lifter jams without causing mechanical damage.

3.5.8 Dual Resolution Diluter Module (DRD)

Description

The Dual Resolution Diluter module, or DRD, is a device which aspirates and/or dispenses volumes of diluent for the instrument's probes. As part of the Fluidics System, two DRDs are resident on the instrument. The DRD on the left aspirates and dispenses large and small volumes for the Sample Probe. The DRD on the right is used for the Reagent Probe. A 3-port distribution valve controls distribution of liquid aspirated and dispensed by the DRD pump. Each DRD has a dedicated valve.

- In the High-Resolution mode, these devices can accurately and precisely move small volumes of fluid (5μl to 265μl) with a resolution of 0.2 μl per motor step.
- **o** In the Low-Resolution mode, larger volumes (up to 3.75 mL) of fluid can be moved very precisely, but with a lower degree of accuracy 2.0 μl per motor step. The larger fluid volume per motor step resolution causes this loss of accuracy.

The DRD uses two pistons, each of which is contained in an acrylic barrel. The lower piston is motor-driven via a lead screw assembly. The upper piston is spring-loaded so that when the lower piston pushes it upwards it is fully loaded.

DRD Mode Selection

The mode selection depends upon the relative position of the two pistons.

- The DRD is in the *Low-Resolution* mode when the two pistons are not in contact with each other. This means that the total cross-sectional area of the lower piston is available for fluid movement.
- The DRD is in the *High-Resolution* mode when the two pistons are in contact with each other.

The lower piston has a slightly larger outer diameter than the upper piston. When they are in contact, only the area of the lower piston that is not touching the upper piston is available for fluid movement. Therefore, only the small annulus of fluid surrounding the upper piston can be displaced when the DRD is in this mode.

Functions

The Dual Resolution Diluter module performs the following functions:

- Aspirates and dispenses all required fluids into the Reaction Tube with accuracy and precision.
- Aspirates and dispenses all required fluids into the Sample Dilution Well with accuracy and precision.
- Aspirates and dispenses all fluids required for washing the probe in order to minimize sample-to-sample carryover.

Functional Components

The DRD module is itself a functional component of the Fluidics System and, as such, has no functional components of its own.

Actuators and Actuator Sensors

The DRDs and valves have the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Sample DRD motor	Stepper motor	Quadrature	Piston home sensor
Reagent DRD motor	Stepper motor	Quadrature	Piston home sensor
Sample Valve motor	Stepper motor	Quadrature	Device home sensor
Reagent Valve motor	Stepper motor	Quadrature	Device home sensor

Design Requirements

The Dual Resolution Diluter module works as part of the Fluidics System and conforms to the following design requirements:

- Pipettes a Ferritin sample within an accuracy range of between 94% and 106% sample recovery and a CV of less than 1.0%.
- Pipettes a TSH reagent within an accuracy range of between 94% and 106% reagent recovery and a CV of less than 1.0%.
- Maintains a leak proof seal around the two pistons for a minimum of 125,000 cycles.

Feedback Requirements

The following sensors are provided to fulfill the feedback requirements for the DRDs (see also **Actuators and Actuator Sensors**, above):

- o *Optical encoders* on both stepper motors to provide position feedback to the control computer on all stepper axes. Both optical encoders provide quadrature output and can detect half steps on a 0.9° stepper motor.
- Home sensors on both stepper motors to provide absolute device positioning information.

Error-Correction Requirements

The DRD module can detect and correct DRD or rotary valve jams without causing mechanical damage.

3.6 Secondary Modules

3.6.1 Introduction

Secondary Modules are defined as those modules that require mechanical or electrical adjustments.

The following are the Secondary Modules of the IMMULITE 2000/2500 Analyzer:

- o Sample Reagent Barcode Reader
- o Sample Dilution Well
- Clot Detection/Sample Manifold Block
- o Reagent Manifold Block
- o Solenoid Pumps
- o Bead Pack Barcode Reader

Each of these modules is explained in detail in the following paragraphs.

3.6.2 Sample Reagent Barcode Reader Module

The Sample Reagent Barcode Reader module, composed of a MicroScan Series 710 laser scanner, is described in the following paragraphs. For complete information about the laser scanner, refer to the MicroScan Series 710 Scanner User's Manual.

WARNING: There are no serviceable parts in the Series 710 barcode scanner. Opening the scan head voids the MicroScan Systems warranty and could expose the user to laser diode power of up to 5mW.

The laser beam can be harmful to your eyesight. Therefore, avoid eye contact with the laser beam and do not point/aim the beam at other people.

Description

The Sample Reagent Barcode Reader is a scanning laser barcode reader that can read specimen, diluent, and reagent barcodes.

Functions

The Sample Reagent Barcode Reader reads

- o sample barcodes
- reagent barcodes
- o sample rack ID

Functional Components

Not applicable.

Actuators and Actuator Sensors

Not applicable.

Design Requirements

The Sample Reagent Barcode Reader conforms to the following design requirements

- reads both specimen and reagent barcodes
- o reads both medium- and high-density barcodes through the Reagent Carousel housing window
- o reads 24 Reagent Wedge barcodes within 10 seconds
- supports the following Barcode Symbology:
 - Code 39
 - Codabar
 - Interleaved 2 of 5
 - UPC/EAN
 - Code 128

Feedback Requirements

Not applicable.

Error-Correction Requirements

Not applicable.

3.6.3 Sample Dilution Well Module

Description

The Sample Dilution Well module is a device which rapidly mixes quantities of specimen, diluent, and water to form a homogenous mixture. These materials are added to the Sample Dilution Well by the Sample Probe and mixing is accomplished by agitating this well. In turn, disposal of excess mixture is accomplished by high-speed rotation of the well.

A dilution requires two cycles:

- O During the first cycle, the Sample Arm pipettes the necessary amount of sample, diluent, and water into the Dilution Well for the desired dilution. When the sample probe is cleaned at the wash station, the Dilution Well thoroughly mixes these fluids.
- The second cycle resembles a normal cycle, except that the sample volume is taken from the Dilution Well rather than the Sample Carousel.

When both cycles are complete and if no additional tests or replicates require the diluted sample, the well spins to remove the diluted sample mixture. The dilution well is then cleaned with probe wash and water.

Functions

The Sample Dilution Well module performs the following functions:

- o thorough mixing of sample with diluent and water in order to achieve a homogenous mixture
- thorough mixing over a range of several dilution ratios
- o effective washing of the dilution well insert when diluted sample is no longer needed

Functional Components

The Sample Dilution Well consists of the following functional components:

- o dilution well housing
- o brushless DC motor
- o dilution well insert

Actuators and Actuator Sensors

The Sample Dilution Well module has the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Dilution Well motor	Brushless DC motor	None	Speed sensor (Hall effect switches on motor)

Design Requirements

The Sample Dilution Well conforms to the following design requirements:

- o mixes sample, diluent, and water to provide a homogenous mixture
- o ejects fluids by spinning at a preset speed
- o controls aerosol formation while mixing and ejecting fluids
- is cleaned sufficiently by fluids from the Sample Arm to yield acceptable sample-to-sample carryover as well as acceptable probe wash carryover
- o operates at two spin speeds
 - slow-speed spin is used for mixing the samples
 - high-speed spin is used for ejecting liquid from the Dilution Well
- o effectively drains, into the liquid waste container, any fluids ejected into the Dilution Well Reservoir
- o does not leak contaminated fluids into the instrument
- o under normal fluid flow and duty cycle conditions, the Dilution Well does not increase sample temperature by more than 15°C above ambient or to a temperature higher than 40°C, whichever is lower

Feedback Requirements

A motor spin speed sensor is provided to fulfill the feedback requirements for the Sample Dilution Well (see also **Actuators and Actuator Sensors**).

Error-Correction Requirements

The Sample Dilution Well module incorporates the following error-correction capabilities:

- detection and correction of incorrect spin speed of Dilution Well
- o detection and reporting of failure to spin Dilution Well

3.6.4 Clot Detection\Sample Manifold Block

Description

The Clot Detection Module uses an analog-to-digital converter to collect output from the pressure transducer while the IMMULITE 2000/2500 is drawing sample from a primary tube. A system of electronics and software amplifies and processes the signal to determine if there is a clot or other obstruction present during the sample draw phase.

The pressure transducer is incorporated within the remote manifold, along with a valve scheme that allows the system to be primed easily. The valve scheme also provides for the isolation of the pressure transducer from the system during the probe washing sequence of the cycle. This prevents overpressurizing of the transducer and thereby extends its life. The transducers have a lifetime of 10⁶ cycles (a cycle is considered pressurization from its minimum- to its maximum- to its minimum-rated pressure).

Functions

The Clot Detection module performs the following functions:

- amplifies output of the pressure transducer to a level that can be adequately read by the analog-to-digital converter
- o analyzes collected data to determine if a clot or obstruction is encountered
- isolates the pressure transducer from the system during the probe washing sequence of the cycle via valve actuations

Functional Components

The Clot Detection module consists of the following major functional components:

- o Sample Manifold
- Analog Fluidics Board
- o Clot Detection Slave Board with software

Actuators and Actuator Sensors

The Clot Detection module includes the following actuators and actuator sensors:

Actuator Name	Actuator Type	Optoencoder	Other feedback
Valve 3 (V3)	Solenoid	None	None
Valve 4 (V4)	Solenoid	None	None
Valve 5 (V5)	Solenoid	None	None

Design Requirements

The Clot Detection module conforms to the following design requirements:

- o accurately detects small volumes of fibrin strands entering the sample probe
- o can be primed easily
- prevents false triggers from occurring (False triggers should occur at a rate of <1 in 10,000 instrument cycles)
- o does not compromise pipetting accuracy or instrument precision
- o can withstand pressure waves generated during the cycle
- o is constructed of material compatible with dH₂O and probe wash

Feedback Requirements

Not applicable.

Error-Correction Requirements

Not applicable.

3.6.5 Solenoid and Linear Actuator Pump Modules

Description

The instrument contains four separate solenoid pumps. Each pump is connected to one of the three probes, which reside at various sites on the Luminometer Chain.

- o One pump dispenses 400µL of water to the Wash Station
- One pump dispenses 200μL of substrate
- One pump dispenses 200µL of Trigger 1 (currently unavailable)
- One pump dispenses 200μL of Trigger 2 (currently unavailable)

Functions

The Solenoid Pumps perform the following functions:

- \circ Dispensing 400 μ L of water per actuation into the tube at the tube wash station to effectively wash the bead
- o Dispensing 200µL of substrate per actuation into a tube at the beginning of the Luminometer chain
- o Dispensing 200µL per actuation of Trigger #1³ at the PMT Read Station
- Dispensing 200µL per actuation of Trigger #2⁴ at the PMT Read Station
- o Performance of actuation and "suck back" from the probe tip to prevent crystallization of material

³ Trigger 1 is currently unavailable.

⁴ Trigger 2 is currently unavailable.

Linear Actuator Pump Module

<u>Note</u>: All IMMULITE 2500 Systems utilize Linear Actuator Pumps. This is the replacement pump for the described Solenoid pump utilized on IMMULITE 2000 systems in the event of a failure.

Description

The instrument contains three separate linear actuator pumps (IMMULITE 2500 Only), two separate linear actuator pumps (IMMULITE 2000 Only). Each pump is connected to one of the three probes, which reside at various sites on the Luminometer Belt.

- Two pumps dispense 400μL of water; these are each connected to their respective Wash Stations IMMULITE 2500 Only
- One pump dispenses 400 μL of water the Wash Station IMMULITE 2000 Only
- One pump dispenses 200µL of substrate

Functions

The Actuator Pumps perform the following functions:

- Dispensing 400μL of water per actuation into the tube at the tube wash station to effectively wash the bead
- o Dispensing 200µL of substrate per actuation into a tube at the beginning of the Luminometer Belt
- o Performance of actuation and "suck back" from the probe tip to prevent crystallization of material

Functional Components

The Solenoid Pumps have the following functional components:

- Solenoid valve
- o 200µl or 400µl (depending on the volume of the pump) bellows
- Solenoid actuator
- o Digital fluidics board
- Probe nozzle and tubing

Actuators and Actuator Sensors

The Solenoid Pumps modules have the following actuators:

- Solenoid valve
- Solenoid actuator

The Solenoid Pumps have no actuator sensors.

Design Requirements

The Solenoid Pumps modules conform to the following design requirements:

- The module must be field-replaceable.
- The module must deliver the desired volume within an accuracy range of $\pm 5\%$ and a CV < 5%.
- The module must have adjustable "suck back" to prevent fluid crystallization at the probe tip.

Feedback Requirements

Not applicable.

Error-Correction Requirements

Not applicable.

3.6.6 Bead Pack Barcode Reader Module

Description

The Bead Pack Barcode reader— which is composed of a Welch Allyn SCANTEAM 3700 CCD Fixed Mount Scanner—is a machine-mount, non-contact barcode scanner, based on a CCD image sensor. This scanner uses the Toshiba TCD1301 CCD for purposes of reading high-density code or far focal planes.

The barcode reader has the following environmental specifications:

o Temperature Range

- *Operational*: 32° F to $+122^{\circ}$ F (0° C to $+50^{\circ}$ C)
- Storage: -40° F to $+158^{\circ}$ F (-40° C to $+70^{\circ}$ C)
- **Humidity:** Relative humidity (non-condensing): 0 to 95%

Note: The unit is not sealed.

Functions

The scanner scans the following angles:

Scanning Angle	Scanner Capabilities
Skew angle (rotation around the X axis)	Skew angle from the scanning plane: +30° to -30°
Pitch angle (rotation around the Y axis)	Scans (beeps) and operates over these pitch angles: +7° to -7°
Tilt angle (rotation around the Z axis)	The tilt angle is limited by the length of the barcode and the height of the bar. The receive path must cross all bars and spaces.

Functional Components

Not applicable.

Actuators and Actuator Sensors

Not applicable.

Design Requirements

The Bead Pack Barcode Reader module conforms to the following design requirements:

- reads either medium- or high-density barcodes
- supports the following Barcode Symbology:
 - Code 128

Feedback Requirements

Not applicable.

Error-Correction Requirements

Not applicable.

3.7 Fluidics

3.7.1 Description

The Fluidics System is a system of tubing, valves, probes, pumps, and reservoirs which provides for the transfer and disposal of fluids throughout the instrument. The following are the components involved in the Fluidics System:

3.7.2 Components

The following components comprise the Fluidics System:

Dispensing

Fluids are dispensed from the following devices. Each fluid, in turn, is pumped by an appropriate device.

- o Sample Probe dispenses or aspirates variable volumes of water, probe wash, diluent, or sample
- Reagent Probe dispenses or aspirates variable volumes of water, probe wash, and Reagent
- Water Probe dispenses fixed volume (400 μL) of water to the Tube Wash Station
- O Substrate Probe dispenses fixed volume (200 μL) of Substrate
- Trigger Probe dispenses fixed volume of Trigger #1 and Trigger #2 (200 μL each)

Disposal

Fluids may be disposed to waste from the following sources:

- o Sample Probe Wash Station
- Reagent Probe Wash Station
- o Dilution Well
- o Tube Wash Station
- Reagent Carousel Drain (for disposal of condensate)

Tubing

Each piece of tubing that comes in contact with liquid used for test processing is made of Teflon. The shape of each piece and the flare at each end are formed by the application of heat.

Each tubing has a fitting that is designed to be "finger" tightened only (except for the probe that has a hexagonal fitting, which can be tightened with a wrench). The proper technique for seating the tubing and tightening the fitting is to:

- 1. Move the fitting approximately 15mm away from the flared end.
- 2. Insert the flared end into the port (of the valve, coupling, etc.) until it "bottoms."
- **3.** Move the fitting into the port and tighten it until it "bottoms."
- **4.** For fittings in valves, tighten the fitting another ½ turn.
- **5.** For fittings elsewhere, tighten until snug.

Rotary and Solenoid Valves

A rotary valve has a molded Kevlar inner piece surrounded by an aluminum body. The piece that rotates inside is Teflon and is driven by a stepper motor within the DRD. These parts are extremely sensitive to over-tightening by the tubing fittings. If over-tightening occurs, the valve allows either air to enter the DRD or water to leak out the valve stem.

For serial numbers D0625 and higher, we have incorporated a rotary valve, which has a machined ceramic disk that is driven by a stepper motor. This disk rotates against a ceramic body, which directs the flow of fluid through the chosen port.

A solenoid valve is a three-way valve composed of three main parts: a 24vdc solenoid, a Viton diaphragm, and the polypropylene valve body. The valve body has:

- o a common port,
- o a normally open port, and
- o a normally closed port

When no power is applied to the valve, the Common and Normally Open Ports are connected. Conversely, when 24vdc is applied to the solenoid, the Common and Normally Closed Ports are connected. The sealing of the Normally Open and Closed Ports is accomplished by a Viton diaphragm. The quality of seal is greatly affected by dirt or any other particles that fall between the diaphragm and the diaphragm seat. For this reason, filters are used on the input lines coming from the Water and Probe Wash Reservoirs.

Probes

A probe is constructed of the following parts:

- o a stainless steel, ME90 coated tube,
- o an inner Teflon tubing
- o an outer Tygon tubing.

The probe is very durable and will last quite a long time under normal operating conditions. In the vertical direction, the probe is very strong. In the horizontal direction, however, the probe will bend, but will usually spring back easily. If the probe were to be permanently bent, it will not position correctly over any of the "X" pipettor locations and must be replaced immediately. Since the probe is washed after pipetting each Reaction Tube, there is no need to remove the probe periodically for cleaning.

Solenoid Pumps

The solenoid pumps are four separate pumps, one for each of the three Signal Reagents and water. Each pump is connected to one of the three probes that reside at various sites on the Luminometer Chain.

Linear Actuator Pumps

The Linear Actuator pumps are three separate pumps. Each pump is connected to one of the three probes that reside at various sites by the Luminometer Belt.

Diluents

Diluents are provided in liquid form and are used by the Processor in combination with water to dilute specimens. They must be furnished as concentrates having at least twice the concentration as that used to dilute specimens.

Reservoirs

Bulk reservoirs are included for the following:

- Distilled Water
- Probe Wash Solution
- Used Reaction Tubes (solid waste)
- Substrate—chemiluminescent alkaline phosphatase (1 reservoir)
- o Trigger Reagent #1⁵ IMMULITE 2000 Only
- o Trigger Reagent #2⁶ IMMULITE 2000 Only
- o Liquid Waste

All bulk reservoirs are level-sensed by using load cells underneath each container. Calibration of these level sensors is part of instrument set-up.

Water and Probe Wash Reservoirs are made of polyethylene material.

- The Water Reservoir holds six liters, or enough for approximately 680 tests.
- The Probe Wash Container holds two liters, or enough for 1650 tests.

⁵ Trigger 1 is currently unavailable.

⁶ Trigger 2 is currently unavailable.

Each container has

- o disposable filters that prevent particles as small as 20 microns from entering the Fluidics System
- o a porous plug in the cap which allows for air to fill the void created by the loss of liquid

The Liquid Waste Container is also made of polyethylene material. It holds six liters; or enough for approximately 1,000 tests. Like the Water and Probe Wash Containers, it has a porous plug for air to escape as the liquid level rises.

3.7.3 IMMULITE 2000/2500 Prime Sequence

The priming sequences are similar for the Sample and Reagent DRD, but not identical. Below are the sequences for both the Sample & Reagent DRD. The sequence starts from the "MIDDLE" position of the DRD.

SAMPLE DRD

- 1. Move rotary valve to PIPETTE TIP position and turn ON V4 and V5 (clot detection valves).
- **2.** Move to TOP position on DRD.
- **3.** Move rotary valve to PROBE WASH position.
- 4. Turn OFF V4 and V5 (clot detection valves)..
- **5.** Draw 0.5 ml of probe wash from bottle.
- **6.** Move rotary valve to WATER position.
- 7. Draw to DRD BOTTOM position to fill with water.
- **8.** Move rotary valve to PROBE WASH POSITION; Turn ON V3 (probe wash valve on Sample manifold).
- **9.** Dispense to MIDDLE position through probe.
- **10.** Turn OFF V3.

The instrument repeats this sequence two times for every one prime cycle.

REAGENT DRD

- **1.** Move rotary valve to PIPETTE TIP position.
- 2. Move DRD to TOP position.
- **3.** Move rotary valve to PROBE WASH position.
- **4.** Draw 0.5 ml of probe wash from bottle.
- **5.** Move rotary valve to WATER position.
- **6.** Draw to DRD BOTTOM position to fill with water.
- **7.** Move rotary valve to PROBE WASH POSITION; Turn on V6 (probe wash valve on Reagent manifold).
- **8.** Dispense to DRD MIDDLE position through probe.
- 9. Turn OFF V6.

The instrument repeats this sequence two times for every one prime cycle.

3.8 Instrument Temperatures

3.8.1 General Information

The IMMULITE 2000/2500 System has four areas of temperature control:

- the Luminometer Chamber (which is heated)
- the Incubator Chamber (which is heated)
- the Substrate Probe (which is heated)
- the Reagent Carousel (which is cooled).

In addition to the areas that are being controlled, three other areas are also monitored:

- the ambient temperature of the Electronics Area,
- the ambient temperature of the Reaction Tube Processing Area, and
- the humidity of the Bead Carousel.

General Temperature Information					
	Luminometer	Incubator Carousel	Reagent Carousel	System Ambient	Substrate Heater
Minimum Operating Temperature	36.90	36.90	4.0	18.0	36.50
Maximum Operating Temperature	37.10	37.10	8.0	32.0	37.50
Lower Alarm Temperature	36.85	36.85	none	none	36.50
Upper Alarm Temperature	37.20	37.20	8.00	34.00	37.50
Maximum Displayable Temperature	43.XX	43.XX	none	none	43.XX
Minimum Displayable Temperature	20.00	20.00	0	0	20.00
Thermistor Resistance	6013 ohms @ 37.00°C.	6013 ohms @ 37.00°C.	N/A	10000 ohms @ 25.00°C.	10000 ohms @ 25.00°C.

Bead Carousel Humidity

Information to be provided at a later date.

3.8.2 Displaying Temperature Information

Temperature and Humidity information can be displayed in either the main operating program or in the Diagnostic Tester. In the main operating program, temperature information is displayed under the pull down menu "Tools", then select "View Temperatures."

In the Diagnostic Tester, a program named "All Temperatures" is available in either Condensed or Detailed run mode. This program will sequentially display all temperature and humidity values.

3.8.3 Temperature Control and Error Reporting

If the temperature-control circuitry cannot establish or maintain one or all temperatures within a certain range, the controlling circuitry assumes that an irreversible condition exists and shuts down the operation of the instrument by placing the instrument in STOP mode. If one or all of the temperatures are out of the normal operating range but not past the shutdown limits, an error is posted on the computer, but the instrument does not enter into shutdown mode.

<u>Note</u>: If a short circuit occurs in one of the transistors that controls the power applied to a heater—causing full power to be applied to that heater—as soon as the temperature of the heated device reaches 45° C, a thermostat terminates the power applied to that heater. When the temperature of the device decreases to 43° C, the thermostat allows current to flow to the heater. While it is not permissible to process Reaction Tubes at this elevated temperature, no damage to the Luminometer or Incubator will occur if these temperatures are reached.

The Luminometer and Incubator are each monitored with two separate averages to determine error conditions. One average is used to determine a Warning error condition, where a message is displayed to the operator, and all tests in process are flagged with a temperature High/Low error. The second average is used to determine a Severe error which will initiate an instrument shutdown, placing the instrument in STOP mode, not allowing tests to be processed until the temperatures are within the accepted range.

Luminometer

Warning Error - Normal Operating Temperature is 36.90° to 37.10°, inclusive. Average is calculated for previous 17 cycles (Moving Boxcar Average). If the average < 36.85° or >37.15° a warning is displayed to the operator. All tubes in the Luminometer and Incubator are tagged with the "Temperature Error" flag.

Shutdown Error - Average is calculated for the previous 5 cycles (Moving Boxcar Average). If the average $<36.5^{\circ}$ or $>37.5^{\circ}$ a severe error is displayed to the operator and the instrument is shut down (STOP mode).

Incubator

Warning Error - Normal Operating Temperature is 36.90° to 37.10° , inclusive. Average is calculated for previous 33 cycles (Moving Boxcar Average). If the average $< 36.85^{\circ}$ or $> 37.15^{\circ}$ a warning is displayed to the operator. All tubes in the Luminometer and Incubator are tagged with the "Temperature Error" flag.

Shutdown Error - Average is calculated for the previous 5 cycles (Moving Boxcar Average). If the average $< 36.5^{\circ}$ or $> 37.5^{\circ}$ a severe error is displayed to the operator and the instrument is shut down.

Reagent

Normal Operating Temperature is 4.0° to 8.0° , inclusive. No average is calculated. A warning is displayed if the temperature is $<4^\circ$ or $>8^\circ$

Substrate

Normal Operating Temperature is 36.5° to 37.5° , inclusive. No average is calculated. A warning is displayed if the temperature is $< 36.5^{\circ}$ or $> 37.5^{\circ}$. Temperature reporting is disabled for 10 cycles after the "Prime" button is pressed.

Ambient

Normal Operating Temperature is 18° to 32°, inclusive. No error checking.

Chapter 4: Pipettor Configurations

4.1 Introduction

This section contains instructions for configuring the Reagent and Sample Pipettors for Allergy and microsampling. These procedures apply to all IMMULITE 2000/2500 Allergy Instruments and/or all Instruments, which have installed a software version capable of microsampling.

4.2 Allergy

Materials

- Diagnostics version capable of setting Allergy positions
- o 400851, Allergen Wedge
- o 400853, Allergen Vials
- o 501805, Septum
- o 200450, Sample Carousel Configuration Fixture
- o 02711, Pipettor Alignment Fixture

Procedure

Allergy positions configured using this document are in addition to all other motor positions configured. Configuration of the Allergy positions assumes that all positions for the Reagent Carousel and Reagent Pipettor have already been configured.

Fixed Parameters

Select the Fixed Parameters menu option from the Main Diagnostics Screen.

Click on the blue bar over the motor list (Slave 0, Slave 1, Slave 2, and Slave 3) to select Slave 1 motors.

Click on "Reagent Arm Z" to view its Fixed Parameters.

Verify that the false level sense positions contain the values in the following table. Enter the values for the "Reagent Pak False level sense" and "Allergen False level sense" if the fields are blank or if they contain different values.

Parameter	Value
Reagent Pak False level sense	3925
Allergen False level sense	5392

Click on the button titled 'Click to Save Fixed Parameters' when done.

<u>Note:</u> Some of the positions in this procedure are set relative to the Laser Barcode Reader. This Reader can be turned on or off by running FILETRANSFER.EXE from the Desktop. Under the menu heading CONTROL UTILITIES, is the option for the Barcode Reader. Click on the correct command to turn the Barcode Reader on or off as desired.

MOTOR CONFIGURATION screen:

A1@Barcode Reader Position:

- 1. Click on "Motor Configuration" button in the main Diagnostics screen.
- 2. Click on "Sample Carousel".
- 3. Place the Sample Carousel Configuration Fixture (200450) into Carousel Position A.
- 4. Home the Sample Carousel.
- 5. Position Rack A, Tube 1 such that the red line from the laser barcode reader is aligned with the small white rib in the center of the rack insert.
- 6. Right click to save this position as "A1@Barcode reader".

The following Reagent Arm and Reagent Carousel positions are best set with the Reagent Carousel Cover removed.

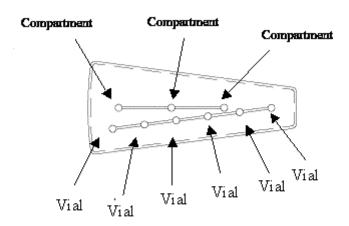
Allergen Bottom Position

<u>Note</u>: It is not required to find the "high" spot in the reagent carousel when setting this position at this time. This position is set relative to the Reagent Bottom position, which takes into account the "high" spot in the carousel.

- 1. Click on the blue bar over the motor list to select Slave 1 motors.
- 2. Click on "Reagent Arm Z".
- 3. HOME the Reagent Arm Z.
- 4. Click on "Reagent Arm X" and HOME the Reagent Arm X.
- 5. Move the Reagent Arm X 200 steps CCW.
- 6. HOME the Reagent Arm X.
- 7. Move the Reagent Arm Z 200 steps DOWN.
- 8. Click on "Reagent Arm Z" and HOME the Reagent Arm Z.
- 9. Click on "Reagent Carousel".
- 10. HOME the Reagent Carousel.
- 11. Move the Reagent Carousel to the "1A Outer" position.
- 12. Move the Reagent Arm X to the "Outer Reagent" position.

- 13. Move the Reagent Arm Z down to the "Reagent Bottom" position. Be sure that the encoder value at the top left of the screen matches the configured value set for the "Reagent Bottom" position.
- 14. Move Reagent Arm Z up 48 steps from the "Reagent Bottom" position. Right click to save this position as "Allergen Bottom".
- 15. Move Reagent Arm Z to the "TOP" position.
- 16. Move the Reagent Arm X to the "Blind Hole" position.

Figure 9
Reagent Arm X Positions



Place Pipettor Alignment Fixture on top of the Probe Cleaning Wedge with the 6 targets is placed in Position 1 of the Reagent Carousel.

<u>Allergen Vial 1</u>- Move the reagent arm and reagent carousel so that the reagent probe will be centered in the target for vial 1 (outermost). Right click to save this position as "Allergen Vial 1".

<u>Allergen Vial 2</u>- Move the reagent arm and reagent carousel so that the reagent probe will be centered in the target for vial 2. Right click to save this position as "Allergen Vial 2".

<u>Allergen Vial 3</u>- Move the reagent arm and reagent carousel so that the reagent probe will be centered in the target for vial 3. Right click to save this position as "Allergen Vial 3".

<u>Allergen Vial 4</u>- Move the reagent arm and reagent carousel so that the reagent probe will be centered in the target for vial 4. Right click to save this position as "Allergen Vial 4".

<u>Allergen Vial 5</u>- Move the reagent arm and reagent carousel so that the reagent probe will be centered in the target for vial 5. Right click to save this position as "Allergen Vial 5".

<u>Allergen Vial 6</u>- Move the reagent arm and reagent carousel so that the reagent probe will be centered in the target for vial 6 (innermost). Right click to save this position as "Allergen Vial 6".

Reagent Carousel Positions:

- 1. Place the Pipettor Alignment Fixture such that the Allergen wedge with the 6 targets is placed into Position 1 of the Reagent Carousel.
- 2. HOME the Reagent Carousel.
- 3. Move the Reagent Carousel to the "1A Outer" position.

<u>Allergen Vial 1</u>- Move the Reagent Arm X to the "Allergen Vial 1" position. Move the reagent carousel and align the target for vial 1 (outermost) such that it is accessible by the reagent probe. Right click to save this position as "Allergen Vial 1".

<u>Allergen Vial 2</u>- Move the Reagent Arm X to the "Allergen Vial 2" position. Move the reagent carousel and align the target for vial 2 such that it is accessible by the reagent probe. Right click to save this position as "Allergen Vial 2".

<u>Allergen Vial 3</u>- Move the Reagent Arm X to the "Allergen Vial 3" position. Move the reagent carousel and align the target for vial 3 such that it is accessible by the reagent probe. Right click to save this position as "Allergen Vial 3".

<u>Allergen Vial 4</u>- Move the Reagent Arm X to the "Allergen Vial 4" position. Move the reagent carousel and align the target for vial 4 such that it is accessible by the reagent probe. Right click to save this position as "Allergen Vial 4".

<u>Allergen Vial 5</u>- Move the Reagent Arm X to the "Allergen Vial 5" position. Move the reagent carousel and align the target for vial 5 such that it is accessible by the reagent probe. Right click to save this position as "Allergen Vial 5".

<u>Allergen Vial 6</u>- Move the Reagent Arm X to the "Allergen Vial 6" position. Move the reagent carousel and align the target for vial 6 (innermost) such that it is accessible by the reagent probe. Right click to save this position as "Allergen Vial 6".

<u>PAK 1@Barcode Reader</u>- Place the Pipettor Alignment Fixture in Position 1 on the Reagent Carousel. Align the red line from the Laser Barcode Reader on the small white line on the spine of the wedge.

The following positions are found under the title heading PAKS 1-12 @READER. This title is reached by clicking on the blue bar titled FIXED POSITIONS.

<u>PAK 1-</u> Place the Reagent wedge with the three targets into Position 1. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.

<u>PAK 2-</u> Place the Reagent wedge with the three targets into Position 2. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.

<u>PAK 3-</u> Place the Reagent wedge with the three targets into Position 3. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.

- <u>PAK 4-</u> Place the Reagent wedge with the three targets into Position 4. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 5-</u> Place the Reagent wedge with the three targets into Position 5. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 6-</u> Place the Reagent wedge with the three targets into Position 6. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 7-</u> Place the Reagent wedge with the three targets into Position 7. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 8-</u> Place the Reagent wedge with the three targets into Position 8. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 9-</u> Place the Reagent wedge with the three targets into Position 9. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 10-</u> Place the Reagent wedge with the three targets into Position 10. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 11-</u> Place the Reagent wedge with the three targets into Position 11. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 12-</u> Place the Reagent wedge with the three targets into Position 12. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- The following positions are configured under the title heading PAKS 13-24 @READER. This heading is reached by clicking on the blue bar titled PAKS 1-12 @READER.
- <u>PAK 13-</u> Place the Reagent wedge with the three targets into Position 13. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 14-</u> Place the Reagent wedge with the three targets into Position 14. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 15-</u> Place the Reagent wedge with the three targets into Position 15. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.

- <u>PAK 16-</u> Place the Reagent wedge with the three targets into Position 16. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 17-</u> Place the Reagent wedge with the three targets into Position 17. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 18-</u> Place the Reagent wedge with the three targets into Position 18. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 19-</u> Place the Reagent wedge with the three targets into Position 19. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 20-</u> Place the Reagent wedge with the three targets into Position 20. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 21-</u> Place the Reagent wedge with the three targets into Position 21. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 22-</u> Place the Reagent wedge with the three targets into Position 22. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 23-</u> Place the Reagent wedge with the three targets into Position 23. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.
- <u>PAK 24-</u> Place the Reagent wedge with the three targets into Position 24. Position the Reagent Wedge so that the red line from the laser barcode reader is aligned with the small white line on the spine of the wedge.

Update File

Click on the "Make .IML File" button to update the .IML file for the changes to be implemented by the control software.

4.3 Microsampling

4.3.1 Configure Sample Pipettor

Enter the Diagnostic Tester, Special Testing Mode, and Motor Configurations:

JAM SIZE Position:

1. Remove / Uninstall Sample Probe.

Home Sample Arm-Z.

Home Sample Arm-X.

Move Sample Arm-X 200 steps CCW.

Home Sample Arm-X.

Move Sample Arm-Z 200 steps DOWN.

Home Sample Arm-Z.

- 2. Click on TOP (DO NOT use HOME to move the sample arm up after performing steps 2 to 8; Use the TOP position instead of HOME).
- 3. Place the Tip Jam Gauge on the sample wash station. Place it so that the shorter part of the gauge is on the bottom and fits snugly in the wash station.
- 4. Attach one clip of the supplied alligator wire onto the Tip Jam Gauge.
- 5. Attach the second clip to the screw that is connected to the ground wire (Green & Yellow wire) of the DRD Module.
- 6. Click on Sample Arm X and select the "Wash Drain" position. The sample arm should move over the sample wash station.
- 7. Click on Sample Arm Z.
- 8. Click on the "Jam Size" button and pay close attention to downward movement of the sample pipettor arm.
- 9. Confirm that as the sample pipettor arm moves down, it touches and tip jams on the jam gauge tool.
- 10. Confirm that the sample arm automatically goes back up to its "Top" position.
- 11. Repeat the steps above (starting from, Click on the "Jam Size") 6 times. Each time, verify that the saved Jam size values are between the range of 0000C2 and 000082 and consistent (±4). Select the "Make.IML Files" button.
- 12. Remove Tip Jam Gauge from the wash station.
- 13. Remove jumper wire alligator clips from the Instrument.
- 14. Re-Install the Sample Probe.

MICROSAMPLE TUBE BOTTOM Position:

1. Click on "Motor Configuration".

Home Sample Arm Z.

Home Sample Arm X.

Move Sample Arm-X 200 steps CCW.

Home Sample Arm-X.

Move Sample Arm-Z 200 steps DOWN.

Home Sample Arm-Z

Move the Sample Arm-Z to the "Top" position.

Move to the Sample Arm X "Outer Sample" position.

- 2. Insert a microsample holder into sample rack A, position 1.
- 3. Insert a 10x50mm tube containing 200uL of Diluent or Control into the holder in rack A, position 1.
- 4. Home the Sample Carousel.
- 5. Move the Sample Carousel 300 steps CCW.
- 6. Home the Sample Carousel, once again.
- 7. Move to the "A1@Pipettor (Sample)" position.
 At this point, the sample arm should be directly centered above sample rack A position 1.
- 8. Select the Sample Arm Z Level sense.

 Note the Hexadecimal value of the encoder in the upper left corner of the screen.
- 9. Move the Sample Arm-Z to the "Top" position.
- 10. Select the Sample Arm Z Level sense making a note of the Hexadecimal value of the encoder each time. Compare the Hexadecimal values and return to "Top" and select Level Sense again if necessary.
- 11. Right-click the value for the "u sample Bottom Find" position after final level sense.
- 12. Confirm that the Hexadecimal value is identical to the u sample Bottom Find value and select the "Make.IML Files" button.

<u>Note:</u> If an error is encountered when the "Make.IML Files" button is selected, it will be necessary to return to the Motor Configuration screen, and select the "Make.IML Files" button again.

CONTROL SIDE ACTIVATION:

- 1. From the desktop screen, open WinNT Explorer, and access C:\DPC\C\File Transfer.exe
- 2. From the File Transfer pull down menu, select "Copy Files".
- 3. Select "User to Control".
- 4. Access the folder C:\Immulite2000\Diagnostics\IML and select the file Microped.iml. Select "Open".
- 5. Select "Send to BIN Directory".
- 6. Press "OK". A message will indicate the "File Transfer was successful".
- 7. Press "OK".
- 8. Exit the File Transfer Utility.

TESTING OF TUBE IN PLACE SENSORS:

- 1. Insert the microsample tubes into the holders and place one holder in position two of racks A through E.
- 2. Move the sample carousel so the microsample tube is in position two of rack A is in front of the inner tube in place sensors. Using the Diagnostic Tester Program, run the program "Sensor Test" and verify the "inner sample hi" sensor detects the tube by turning red.

<u>Note:</u> The "inner sample lo" sensor may not detect the microsample tube holder but this is expected. It is not required that the inner lower sensor detects the microsample holder.

- 3. Repeat the previous step for racks B through E.
 - If the inner sensor fails to detect the tube at any of the positions, the inner sensor may need to be adjusted or replaced. When adjusting the inner sensor do not move the sensor so close that it will interfere with a Diluent tube. When replacing the sensor, use the new part number 901791, designated with a green dot on it. These sensors are pre-tested to detect microsample tubes on the inner row.
 - If the inner sensor was adjusted or replaced, repeat the test procedure again.
 - If the existing inner sensor was found to be operational, please designate the sensor with a supplied green dot.

MICROSAMPLE CONFORMATION PROCEDURE:

Refer to Kit 422085, document 600280, Micro-Sample Configuration Test Procedure.

If false clot detection errors are encountered during this testing, please repeat the "Jam size" procedure again.

4.3.2 Confirm Microsample Configuration

Materials

- o IMMULITE 2000/2500 Chemistry Kit with a sample size of 5 uL, 10uL, 15 uL, 20 uL or 25 uL
- Multi-analyte high level control
- o 400881, Insert Adapter and Label Assembly (3)
- o 902113, 10 x 50mm Microsample Tubes (3)
- o 12 x 75mm Tubes (3)
- Pipettor capable of accurately dispensing up to 400 uL.

Procedure

Microsample Dead Volume Testing

According to the following chart, dispense the appropriate amount of the high-level multi analyte control into three microsample tubes. If available, please choose an Assay with a sample size of 5 uL, as this will best determine if Micro-sampling is configured properly.

Assay Sample Size	Amount of uL in tube	Number of Tests Ordered
5	60	6
10	85	6
15	110	6
20	135	6
25	160	6

- 1. Load the microsampling tubes into the holders and place them on the Sample Carousel.
- 2. Dispense 400 uL of the high level multi-analyte control into each of three 12 x 75 mm tubes and place them on the Sample Carousel.
- 3. Request 6 replicates, selecting the appropriate chemistry kit for the three Microsampling tubes.
- 4. Request 4 replicates of the same assay for the three 12 x 75 mm tubes.
- 5. Confirm that all tubes are identified correctly graphically. Microsample tubes should be represented as squares on the Sample Carousel screen, instead of circles.
- 6. Visually confirm that the pipettor goes through the bottom finding routine for the three Microsampling tubes with less than 200 uL of control during each pipetting sequence.

- 7. The Instrument must successfully pipette at least 4 replicates from each tube.
- 8. Each Microsample tube must be detected by the system as insufficient sample and marked as such during either the last or second to last ordered replicate.
- 9. Calculate the mean and %CV for all replicates from the three Microsampling tubes.
- 10. Do not use the last resulted replicate from each tube, in the calculation of the mean.
- 11. The result of the last replicate from each of the Microsampling tubes must be within 3SD of the mean.
- 12. Calculate a single mean of the twelve values for the 12 x 75 mm tubes (Mean 1).
- 13. Calculate a single mean of the twelve values, the first four from each of the three Microsampling tubes (Mean 2).
- 14. Calculate the % difference: ((Mean 1 Mean 2)/ Average of Mean 1 and Mean 2) * 100.

This % difference of the two means (ignoring whether it is positive or negative) must be <8%.

If any of the above-mentioned criteria fails to happen, repeat the Microsampling Configuration Procedure and then repeat the microsampling dead volume testing procedure.

Chapter 5: Printed Circuit Boards

5.1 Introduction

This section contains descriptions of the Printed Circuit, or PC boards. Refer to the Assembly and Schematic Manual for actual drawings of the boards.

5.2 Power Supply Chassis

The following paragraphs describe the AC and DC power distribution for the Instrument.

AC Power Distribution

220VAC enters the IMMULITE 2000/2500 through the AC entry module in the rear of the Instrument and is carried to a circuit breaker/power switch at the front of the unit. The power is then carried back to the rear of the Instrument and connected to the isolation/step-down transformer, which converts the 220VAC to approximately 115VAC. The voltage is then distributed, through fuses and connectors on the AC Power Distribution PC board, to each major assembly requiring 115VAC.

Confirming AC Voltages

To confirm AC voltages, use a multimeter rated to handle 250 VAC and do the following:

- 1. Measure the input voltage at the white screw terminals labeled LI, L2(N), G on the isolation /step-down transformer, located at the rear of the IMMULITE 2000/2500.
 - L1 to L2 = line voltage from the wall
- 2. Measure the output voltage at the white screw terminals labeled L, N, G on the isolation/step-down transformer.
 - L to N = 100 to 120 VAC, depending on the input wall voltage

Checking Fuses

The AC Power Distribution PC Board has six fuses that protect the unit from failure. To check these fuses, do the following:

- 1. Determine that 115VAC is being delivered to the board by using a multimeter to measure the blue and brown wires across J10.
- **2.** To locate the failed fuse, determine which part of the Instrument is not working and, looking at the labels on the PC board, find the fuse associated with that part (refer to Assembly Drawing 450132). For example, if the fans are not on, check F2 AIR INTAKE FANS.
- **3.** Replace the fuse with the unit powered down. Then power on the unit. If the fuse blows out, remove its associated connector (for example, F2 provides power to J9) and determine why the device is causing the fuse to blow open.
 - When all of the fuses are working, all side fans should be spinning. When the DC power supply is working, then all the power supply fans and CPU fans should be spinning and all the DC Power Distribution PC board LEDs should be ON.

DC Power Distribution

The VICOR MagPAC—black power supply, mounted on the right side wall of the chassis—produces five different DC voltages. These voltages and their associated power-sense lines are connected to the Power Distribution Board: 450134 PCB Assembly for AT Style Chassis, 450150 for ATX Style Chassis and the 450188 PCB Assembly for the IMMULITE 2500.

The 400803 Cable Assembly Remote Sense *must* be connected in order for the VICOR MagPAC to properly supply power. There are seven fuses and nine LEDs for the 450150 PC board. The 450150 PC board has six fuses and eight LEDs to protect and display the power status, as described below:

- o L1 is an indicator for the +24 VDC power, distributed from this board by J2. This indicator has no associated fuse because of the high (24-amp) current. Safety shutdown is accomplished through the VICOR's output "overvoltage" and "overcurrent" protection features.
- L3 indicates +12 VDC and L4 indicates -12 VDC. Fuses F3 and F4, respectively, provide protection for these LEDs.
 - +12 VDC and -12 VDC is distributed to five of the six red power connectors on this PC board. If a short occurs on any of the connected assemblies, you must isolate the cable assembly, then the board, on which the short circuit is located.
- L2 indicates that +5VDC is being supplied to the PC board.
- L5, L6, L7, and L8 each display that +5VDC is passing through its associated fuse and is being routed to a particular connector(s).
- O CPU1, CPU2, Hard drives/CD/Floppy, and Drive PC boards each have their own LED and fuse in order to help isolate the problem in the event of a short circuit. If the LED is off, the fuse is blown, which means that a short circuit has occurred in the related area. If a short occurs but does not cause a fuse to open, the VICOR output "overvoltage" and "overcurrent" protection turns off the power and the Instrument must be powered down completely in order to reset it. White test points are labeled with their associated voltages.

Isolating a Short Circuit

To isolate a short circuit inside the Instrument after either a fuse has blown or the VICOR supply has shut down, do the following:

- 1. Disconnect all cables going to the red square and rectangular power connectors on the DC Power Distribution PC board.
- 2. Check and replace any previously blown fuses, indicated by an LED that is not on.
- 3. Power up the Instrument and determine that all of the LEDs turn on.
- **4.** Turn off the power.
- **5.** Connect one cable at a time and power up the unit. Check the LEDS, turn the unit off, and then make another connection.
- **6.** Repeat this sequence until a cable assembly blows a fuse. Then remove the connector, replace the fuse, and determine the modules that are on this cable assembly and which module would cause a fuse to blow. Typical reasons for a blown fuse include crushed sensor wires, lead falling into the PC boards, and leaks from the Fluidics system.

PMT Power Supply

The F3 fuse and the J1 connector of the AC Power Distribution PC board power the PMT Power supply. The wire harness connects to the PMT Power Supply board on the J1 connector. The AC is then filtered and sent to the linear power supply. This power supply provides +5VDC and -5VDC to the PMT, data acquisition PC board, and analog bulk fluidics PC board. If none of these three are working, check the fuse, check the cable and, finally, check the power supply. (NOTE: The PMT Power Supply uses an isolated GND. This isolated GND must be used when measuring voltages from the PMT Power Supply).

CPU Power Considerations

Each CPU board receives +5, +12, -12, and a "Power Good" signal from the Power Distribution board. Again, +5VDC is fused separately for each CPU board, but +12 and -12 share a common fuse. Both CPU boards also share a "Power Good" signal from the VICOR MagPAC power supply. This +5 signal is sent when the +5VDC module is working properly. This connection is made to the Instrument's board at J8 and must be connected in order for the CPUs to begin their boot sequence. For ATX electronic style chassis, a 3.3 VDC module was added to the VICOR MagPAC power supply.

Later chassis' utilize a separate power supply for the User Side Motherboard that generates the +3.3, +5,+12,-12 VDC. With this additional power supply there is no longer a 3.3 VDC Module in the VICOR MegPAC Supply.

5.3 The Control PC

The Control PC is a Pentium motherboard, running at 75Mhz, or higher. The Control PC is running a DOS operating system. For serial # D0404 and higher we utilize a single board computer (SBC).

The Control PC is responsible for controlling all mechanical functions and temperature control of the system. The operator has no direct access to the Control PC. All data transfer is made via the User PC common memory PCB and the file transfer utility.

The Control PC has the following resources;

- 2 stepper motor controller PCBs IMMULITE 2000
- 3 stepper motor controller PCBS IMMULITE 2500
- temperature processor PCB
- o clot detection PCB
- temperature processor and clot detection PCB IMMULITE 2500
- graphics PCB* (unless an ATX Chassis, then graphics card is incorporated on SBC).
- o 6" Monitor Cable Added with newer electronic chassis'
- 6" Keyboard Cable Added with newer electronic chassis'

The control PC does *not* have the following resources installed:

- o floppy disk
- keyboard
- o mouse
- monitor

The service technician may install these optional items in order to diagnose problems on the Control PC and the ISA Bus.

5.4 ISA Slot and IRQ Verification

To check that the Control PC System PCB is recognizing all Slave PCBs, a Diagnostic Utility program, called "PNP," can be run to display the system status. To execute the program, a monitor and keyboard must be connected to the Control PC.

<u>Note</u>: If using the User PC Monitor and Keyboard, remember to disconnect power to the User PC hard drives, to prevent the Windows NT boot process)

After booting the Control PC, press "escape," to terminate the active program and return to the C:\BIN> prompt. At this prompt, type "PNP," then press "enter."

The following information should appear for the IMMULITE 2000:

```
      ADDRESS: D800, IRQ 11
      (slave0)

      ADDRESS: D840, IRQ 12
      (slave1)

      ADDRESS: D880, IRQ 15
      (slave2)

      ADDRESS: D8C0, IRQ 10
      (slave3)

      ADDRESS: D900, IRQ 5
      (slave4 Temp Control)

      ADDRESS: D940, IRQ 7
      (slave5 Clot Detection)
```

The following information should appear for the IMMULITE 2500:

```
ADDRESS: D800, IRQ 11 (slave0)
ADDRESS: D840, IRQ 12 (slave1)
ADDRESS: D880, IRQ 15 (slave2)
ADDRESS: D8C0, IRQ 10 (slave3)
ADDRESS: D900, IRQ 6 (slave4 Temp Control)
ADDRESS: D940, IRQ 7 (slave5 Clot Detection)
ADDRESS: D9800, IRQ 9 (slave6)
```

If one, or more, of the IRQs does not appear, it will indicate the Slave PCB is not recognized by the Control System PCB. First, try reseating the Slave PCB in question. Also, verify that the jumper configuration on the Slave PCB is correct.

If this is not successful, a Slave PCB or System PCB problem is suspected.

Control PC Bios Setup Information

<u>Note</u>: If the Control PC Motherboard is replaced, or if the CMOS battery power is interrupted, the BIOS information must be entered in the Setup Utility.

The following BIOS Configurations are for the AT Style Chassis (B0001 - D0403) on the IMMULITE 2000.

For the BIOS Configurations of the IMMULITE 2500 please refer to Chapter 6.

IMMULITE 2000 CONTROL PC BIOS

For AT Style Chassis (B0001 - D0403)

Main Advanced Security Exit

System Date Mar 03 1997 System Time 14:42:47

Floppy Options Press Enter

Primary IDE Master Quantum Fireball_**T**Primary IDE Slave Not Installed
Secondary IDE Master Not Installed
Secondary IDE Slave Not Installed

Language English (US)
Boot Options Press Enter

Video Mode EGA / VGA Mouse Not Installed

Base Memory 640 KB Extended Memory 7168 KB

BIOS Version 1.00.05.BR0

Boot Options

First Boot Device Hard Disk
Second Boot Device Disabled
Third Boot Device Disabled
Fourth Boot Device Disabled

System Cache Enabled
Boot Speed Turbo
Num Lock Off

Setup Prompt Enabled Hard Disk Pre-Delay Disabled

Typematic Rate Programming Default
Scan User Flash Area Disabled

Control PC Bios

	Main	Advanced	Security	Exit	
	Advance	Proc	essor Type sor Speed Cache Size figuration guration Configuration	Pentium (R) Family 133 MHz 256K Press Enter Press Enter Press Enter Press Enter Press Enter Press Enter	
╽┕					┙╽

Peripheral Configuration

		_
Configuration Mode	Manual	
Primary PCI IDE Interface Secondary PCI IDE Interface Floppy Interface	Enabled Disabled Disabled	
Serial Port 1 Address Serial Port 2 Address Serial Port 2 IR Mode Parallel Port Address Parallel Port Mode	COM1 3F8 IRQ4 COM2 2F8 IRQ3 Disabled Disabled Bi-directional	

Control PC Bios

5-6

Advanced Chipset Configuration

Base Memory Size 640 KB

ISA LFB Size Disabled

Video Palette Snoop Disabled
Latency Timer (PCI Clocks) 66

PCI Burst Enabled

Bank 0 SIMM Detected EDO Mode
Bank 1 SIMM Detected None Installed

Power Management Configuration

Advanced Power Management Disabled

Control PC Bios

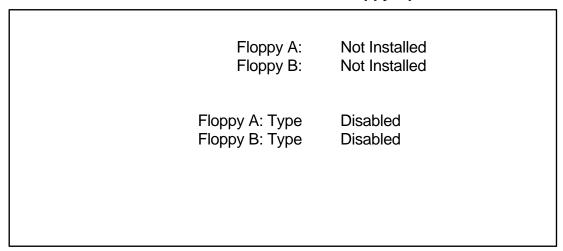
Plug and Play Configuration

Configuration Mode	Use Setup Utility
ISA Shared Memory Size ISA Shared Memory Base Address	64 KB D0000h
IRQ 5 IRQ 7 IRQ 9 IRQ 10 IRQ 11 IRQ 12 IRQ 15	Used By ISA Card Used By ISA Card Available Used By ISA Card

Main	Advanced Security	y Exit
	User Password i Administrative Password i	
	Set User Password Set Administrative Password	

Control PC Bios

Floppy Options



Communication between the control PC motherboard is accomplished via the following standard ISA signals:

- the address lines A0 –A19
- the data bus D0 D7
- the control bus, which comprises
 - the memory read signal (\smer)
 - the memory write signal (\smew)

The ISA bus also contains Interrupt request lines $IRQ_0 - IRQ_{15}$. These hardware lines are used to interrupt the PC when a slave attempts to acknowledge or provide some information to the PC. Not all IRQs are available to the inserted cards since some of them are allocated to on-board resources such as the hard drive, real-time clock, etc. In general, IRQs 10-12, 15, 5, 7, 9, and 6 are used. This furnishes a more-than-adequate choice and the slave boards are "jumpered" accordingly.

Two-way communication between the ISA bus and a slave processor is accomplished via a dual-port RAM, or DPR, residing on the slave board.

- The *processor* is a Zilog Z8 8-bit microprocessor, which has six hardware interrupt lines, of which four are available on external pins of the chip. Thus, the processor, too, can be interrupted.
- The *dual-port RAM* is a 1K, 8-bit device; its locations are accessible from two ports. Two buses are attached to the DPR, one on the left and one on the right
- The ISA bus is connected to the DPR using the following:
 - A0 A9 of its address (1K addressing)
 - the control bus signals (\memw and \memr)
 - a chip-select signal, derived from the 20 address lines of the lower 1 megabytes of the PC's memory.

A programmable logic device, or PLD, on the slave boards decodes the chip-select signal. The slave DPR to which information is written is dependent on the chip select. The address locations of the various slave boards are provided in the following tables for the IMMULITE 2000 and IMMULITE 2500.

IMMULITE 2000

Slave Number	Address	Accesses
Slave 0	D8000	o Sample pipettor X & Z
		• Sample valve
		o Sample DRD
		Sample Carousel
Slave 1	D8400	• Reagent pipettor X & Z
		o Reagent valve
		o Reagent DRD
		• Reagent Carousel and Pack lid activator
Slave 2	D8800	Bead Carousel & bead dispenser
		• Tube indexer
		• Tube transport
		• Processor shuttle
		o PMT shuttle
Slave 3	D8C00	• Luminometer chain
		• Luminometer shuttle
		• Tube lifter
		• Geneva indexer
		Luminometer attenuator
Slave 4	D9000	Temperature/PMT
		o Dilution well
		• A/D and D/A controls
Slave 5	D9400	• Clot detection
Slave 6	D9800	o spare

IMMULITE 2500

Slave Number	Address	Accesses
Slave 0	D8000	o Sample pipettor X & Z
		o Sample valve
		o Sample DRD
		o Sample Carousel
Slave 1	D8400	• Reagent pipettor X & Z
		• Reagent valve
		o Reagent DRD
		Reagent Carousel and Pack lid activator
Slave 2	D8800	o Bead Carousel & bead dispenser
		• Tube indexer
		• Tube transport
		o Incubator Belt 1
		o Incubator Belt 2

Slave Number	Address	Accesses	
Slave 3	D8C00	0	Luminometer Belt
		0	Tube lifter 1
		0	Tube lifter 2
		0	Luminometer disk
		0	PMT attenuator
		0	PMT transfer
Slave 4	D9000	0	Temperature/PMT
		0	Dilution well
		0	A/D and D/A controls
Slave 5	D9400	0	Clot detection
Slave 6	D9800	0	Processor Shuttle
		0	Incubator belt transfer
		0	Wash 1 transfer
		0	Wash 2 transfer
		0	Exit transfer

The same locations of the dual-port ram can be accessed by the Z8 processor on the slaves. The Z8 bus—namely, ZA_0 - ZA_9 , along with the control bus R/W, the write and read signals, and the right-hand chip select (\cs)—serve to access the dual-port Ram. The chip select for the DPR as well as the various other I/O devices on the slaves is derived again by a PLD

<u>Note</u>: two sides should never access the same location of 1K DPR *at the same time*. The side that gains access first, whether reading or writing, has control of the memory. Thus, if a read of a location is in process and a write is initiated at the same time from the other side, the write will not get through. In IMMULITE 2000/2500, great efforts have been made to avoid this problem by proper "handshaking" and allocating areas of RAM to which the ISA bus writes and areas to which only the slave writes.

5.5 Mailboxes and Generating Interrupts

The last two locations of the DPR—specifically, 03FE and 03FF (H) — contain a hardware link. This link operates as follows:

- **o** When the ISA bus writes a byte to location 3FF, the INTR port on the DPR chip goes low. The output of this port is tied to one of the external interrupts of the Z8. Resetting this port back to a high can be accomplished only if the Z8 side *reads* location 3FF.
- O Location 3FE has a similar function except, in this case, the Z8 must write any byte to 3FE. This forces the INTL port of the DPR to go low. This signal is routed to one of the interrupt lines on the ISA bus. Resetting of this port back to high can be accomplished only if the ISA bus *reads* location 3FE.

• In this manner, each side can signal the other that it wants to make use of the DPR. Additional safeguards are in place to assure that both sides do not access the same location at the same instant.

5.6 The 32K Common Memory Board

The 32K DPR board provides a means of communication between the control and user's PCs. This board has the following characteristics:

- The RAM board resides in one of the slots in the user's PC.
- The control side's DPR interface resides on the temperature/PMT slave, which is plugged into one of the control computer's ISA slots.
- A 34-pin ribbon cable between the two boards joins the two motherboards.
- This board contains the entire "tube" database, which is maintained by the control CPU. This database contains information for every tube in every position on the Instrument. The control CPU also maintains the following:
 - motor status
 - sensor status
 - last spin speed
 - CPS from the PMT
 - temperature information
 - other information

The 32K DPR is also used to send "messages" between the two systems.

These messages include

- Instrument commands (e.g., Prime, Stop, etc.)
- sending of files from one system to the other (e.g., software updates)
- The communications protocol used between the two PC motherboards is based on arbitration hardware/software that uses semaphores.

The 32K dual-port RAM (DPR) is accessed by the following:

- the ISA bus of the control PC motherboard on one side
- the ISA bus of the user PC on the other side

Each ISA bus accesses the dual-port RAM via the following:

- o its address bus (A0 A19)
- data bus (D0 D7)
- the control bus (\SMER, memory read, and \SMEW, memory write)

A PLD, residing on the common memory board plugged into the user PC, selects the DPR by decoding one of five possible addresses for the DPR. These addresses are memory-mapped to one of these locations.

- o C8000
- o D0000
- o D8000
- o E0000
- o E8000

One of these locations is selected via the setting of a three-position dipswitch on the board. The actual 32K DPR chip resides on this board.

Temperature/PMT Processor Board

The Temperature/PMT processor board contains a PLD equivalent to that on the common memory board, which can select one of the five memory areas, starting with C8000, as described above.

The signals originating on this board generate the following:

- o a buffered address bus of the control PC
- o a buffered, bi-directional data bus
- o a buffered control bus, containing the read and write signals from the control PC

5.7 Semaphores

The *semaphore* is a cross-coupled memory location that resides within the DPR chip and that operates in the following way:

The PLDs on both the common memory board and the temperature/PMT processor board decode a semaphore select signal that enables either bus to read or write to one of eight semaphore locations. If one of the ISA buses attempts to access the DPR, the bus writes a 0 (zero) to one of the eight semaphores. The following table describes what subsequently occurs.

If the bus reads	Then
0	Access to the DPR is available.
1	The software assumes that the other ISA bus has access to this semaphore and it should neither read nor write to the mutually agreed-upon area of memory.

If access is achieved, a 0 (zero) is read back and the requesting ISA bus can then read or write freely to the area of memory that has been allocated by the software to that semaphore.

When all transactions are completed by the requesting ISA bus on the DPR, the bus must release the semaphore by writing a 1 (one) to it. Once the semaphore is released, the other side (i.e., the ISA bus) can access the semaphore and, by mutually agreed-upon protocol, perform transactions on the DPR.

Because there are eight cross-coupled semaphores, eight areas of memory can be selected within the software protocol in order to gain permission for transactions in that particular memory area.

5.8 The User PC

The user PC on the IMMULITE 2000 is a Pentium Pro motherboard, running at 200Mhz or higher. The User PC is running a Windows NT operating system.

The user PC on the IMMULITE 2500 uses a Pentium III or higher processor. The User PC is running a Windows XP operating system.

The user PC provides the human interface to the system. This means that all software and diagnostics are ordinarily run through the user PC. Commercially available boards are plugged into the user PC. These boards consist of at least the following:

- o graphics board
- o network card
- o sound card
- o octal serial card (eight channels of RS232)

The common memory 32K card, discussed above, is the only card that is proprietary to the PC; it plugs into one of the ISA slots on the motherboard.

The User PC motherboard also has the following resources:

- o keyboard
- o trackball
- o touch screen monitor
- o dual hard drives
- o floppy drive
- o CD ROM drive
- Printer
- o 2D CCD barcode scanner

User PC Bios setup Information

<u>Note</u>: If the User PC Motherboard is replaced, or if the CMOS battery power is interrupted, the BIOS information must be entered in the Setup Utility.

The following BIOS Configurations are for the AT Style Chassis (B0001 – D0403) on the IMMULITE 2000.

For the BIOS Configurations of the IMMULITE 2500 please refer to Chapter 6.

IMMULITE 2000

USER PC BIOS FOR AT STYLE CHASSIS (B0001 – D0403)

Main Advanced Security Power Boot Exit System Time: [16:37:26] System Date: [07/21/1997] Diskette: [1.44 MB, 3½"] IDE Adapter 0 Master (C: 4000 MB) IDE Adapter 0 Slave (D: 4000 MB) IDE Adapter 1 Master (None) IDE Adapter 1 Slave (None) [EGA / VGA] Video System: Video BIOS: [Shadowed & Cached] System BIOS: [Shadowed & Cached] External Cache: [Enabled] System Memory: 640 KB Extended Memory: 63 MB

Main Advanced Security Power Boot Exit

Warning!

Setting items on this menu to incorrect values may cause your system to malfunction.

Serial port A: [COM1, 3F8, IRQ 4]

Serial port B: [Disabled]
Serial port B MODE: [COM Port]

Parallel port: [LPT1, 378, IRQ 7]

Parallel port MODE: [AT]
Diskette controller: [Enabled]
Integrated PCI IDE: [Both]

IRQ 12: [Used by PS/2 Mouse]

Plug & Play O/S [No]
Reset Configuration Data [No]
Large Disk Access Mode [Other]
DRAM Type: [Non-Parity]

User PC Bios

Main	Advanced	Security	Power	Boot	Exit

Supervisor Password is
User Password is
Set Supervisor Password
Set User Password
Press Enter
Press Enter

Password on boot: [Disabled]

Diskette access: [User]
Fixed disk boot sector: [Normal]
System backup reminder: [Disabled]

Main Advanced Security Power Boot Exit

APM: [Disabled]

Power Management Mode: [Disabled]

Management) allows APM

Standby Timeout:
Suspend Timeout:
Disabled
Standby CPU Speed:
Maximum
Fixed Disk Timeout:
Disabled
ON

Mouse Wakeup Events [PS/2 (IRQ12)]

Standby Break Events

IRQ3: [Disabled]
IRQ4: [Enabled]
IRQ5: [Disabled]
IRQ6: [Disabled]
IRQ7 [Disabled]

User PC Bios

Main Advanced Security Power Boot Exit

Boot Sequence: [Hard Drive]
SETUP prompt: [Enabled]
POST Errors: [Enabled]

Floppy check: [Enabled]

Numlock: [Off]

User PC Bios

5.9 Dehumidification

The dehumidification capabilities of the IMMULITE 2000/2500 are described in the following paragraphs.

The beads inside their Packs must be kept at a relative humidity (RH) below 20% to achieve long-term stability.

The IMMULITE 2000/2500 uses both a passive method and an active method to keep the humidity low.

- The *passive method* is to pack the Bead Packs with desiccant, which serves to keep the RH below 20%.
- The active method is described below.
 - A drying box, containing Bentonite clay—which can be regenerated—is mounted on the Bead Carousel. Regeneration is achieved by the following method:
 - The saturated clay is heated to about 110°C. The heat drives the moisture out of the desiccant and a fan circulates outside air through the clay to remove the moisture. When the desiccant has cooled, it is ready to be used again.
 - In the drying mode, the air inside the Bead Carousel (i.e., the volume occupied by the Bead Packs) is recirculated through the active desiccant to cause drying.
 - To keep the drying process continuous, two containers of the Bentonite are available. While one is drying the Bead Carousel, the other is being regenerated.
 - A motorized valve controls the diversion of air through the desiccant.
 - → If the drying agent is being regenerated, the valve recirculates the air with outside air.
 - → If the drying agent is in the drying mode, the valve recirculates air through the Bead Carousel.

Controls

The following controls are provided for the components used to dehumidify the IMMULITE 2000/2500:

- Two heaters, composed of power resistors, are turned on individually via a control line from the temperature/PMT board. These control lines turn on an FET for each of the heaters and supply about two amps @ 24 volts to the affected heater.
- Another control is provided to turn the fans on and off.
- Motor control is achieved with three control lines. These lines are
 - motor direction 1,2
 - motor enable

All controls are derived from the temperature/PMT board and transmitted to the dry box as serial information. A serial-to-parallel converter on the Bead Carousel board converts the serial port information to parallel port information that drives the power drivers.

5.10 Temperature Control

The IMMULITE 2000/2500 requires temperature control. The regions to be controlled and their specifications are shown in the following table:

Instrument Region	Required Temperature Range
Tube processor	37°C ±0.1°
Luminometer	37°C ±0.1°
Reagent carousel	6°C ±2°
Substrate heater	37°C ±0.5°

The methods used to control these regions vary slightly.

- o IMMULITE 2000 The tube processor, luminometer, and substrate heater use thermistors and a single 18-bit dual-slope analog-to-digital (A/D) converter with a serial interface. The dual-slope conversion technique is used where precision and accuracy are most important.
- o IMMULITE 2500 The incubator, luminometer, and substrate heater use thermistors and a single 18-bit dual-slope analog-to-digital (A/D) converter with a serial interface. The dual-slope conversion technique is used where precision and accuracy are most important.
- The reagent carousel uses a semiconductor temperature sensor and a 12-bit serial successive approximation A/D converter. The successive approximation technique is used because it permits a wide range of temperature specifications.

Reagent Carousel Temperature Control

Temperature control for the Reagent Carousel is described in the following paragraphs.

The Reagent Carousel is designed to keep reagents on board and refrigerated for an indefinite period of time. The control temperature is 6° C. This temperature is sensed with a National Semiconductor LM35 sensor. This device is accurate to $\pm 0.5^{\circ}$ C, which is more than sufficient for the Reagent Carousel's specification of $\pm 2^{\circ}$ C. The output of this device is a linear + 10mv/ $^{\circ}$ C.

A MAXIM MAX187 performs data conversion. This device has an on-board voltage reference of 4.095V, used to excite the LM35. The output of the LM35 is fed directly to the input of the MAX187. At 6°C, the input signal is 60mV and does not require further amplification. The MAX187 is a 12-bit successive approximation device. The 12 bits provide a resolution of 1 bit per mV of signal.

The converted data is serially transmitted to the temperature control processor board. The Z8 microcontroller is programmed to provide on/off-type control to the Reagent Carousel. When the temperature of the Reagent Carousel rises to 8°C, the Z8 sends a control signal to turn on the power transistors that drive the thermoelectric coolers (TED). These coolers are used to refrigerate the reagent chamber. When the temperature of the Carousel drops below 4°C, the Z8 turns off these power transistors, thereby preventing the reagent chamber from any further cooling.

Luminometer, Tube Processor, and Substrate Heater Temperature Control

Temperature control for the Luminometer, Tube Processor, and Substrate Heater is described in the following paragraphs. The Luminometer, Tube Processor, and Substrate Heater all require more stringent temperature control than does the Reagent Carousel. Although all three modules have a common set point temperature of 37°C, they differ slightly in the type of algorithm used to accurately control their temperatures. Because of the need for accuracy and precision, a thermistor is used to sense the temperature of each of these modules. The thermistors' characteristics are linearized with a bridge circuit; each thermistor has its own bridge.

The output of the bridge is a differential voltage, proportional to temperature. This signal is multiplexed with the other bridge signals. The multiplexed output is then selected and fed directly into the dual-slope A/D converter. No amplification or other signal conditioning is performed on the signal before it is converted to digital data. Although dual-slope conversion is slow, it is very precise and naturally immune to noise.

The digitized data is serially transmitted to the Z8 processor over the synchronous serial data bus. The Z8 microcontroller then processes the data, using a different algorithm for each region of control. In general, a PID, proportional, integral, and differential control method is used to maintain the tight tolerances on temperature control.

The Z8 also controls the heat delivered to the Substrate Heater, Luminometer, and Tube Processor. The Z8 produces a pulse-width modulated (PWM) signal for each of the three heaters. The PWM signal is created through the use of a UPD71054 counter/timer, whose count values are varied by the Z8. The signal is fed to the power transistors that are used to turn on the three electric heaters. When the heaters are cold-started, the PWM duty cycle is virtually 100% on. As the set point for control is reached, the PWM duty cycle is continuously varied in order to produce just the correct amount of heat necessary to maintain the set point temperature.

Temperature and Humidity Sensors

The following sensors are provided to monitor temperature and humidity in various sections of the Instrument:

Temperature Sensors

Embedded inside each of the heaters are a thermistor and a thermostat. The functions of each follow:

- When the temperature reaches about 110°C, the *thermistor* abruptly changes from its normally very high resistance to nearly 0 ohms. This information is sent back to the temperature processor as a digital signal. The temperature processor then uses this information to turn the respective heater on and off very rapidly in order to keep the desiccant at 110°C.
- A *thermostat*, in series with the heaters selected to open at about 160°C, has been incorporated to safeguard the unit from overheating. An available (digital I/O) feedback signal alerts the temperature processor that one or both of the heaters are in this "over temperature" mode.

Humidity Sensors

A *humidity sensor* in the Bead Carousel develops a linear voltage proportional to the relative humidity (RH). This voltage is converted, via an on-board analog-to-digital (A/D) 12-bit converter, into a digital serial signal that is then sent via the serial cable to the temperature/processor board. In this way, the following controls are achieved:

- The temperature/processor can monitor the status of the RH in the Bead Carousel.
- The software can use this information for display purposes or for alerting the user of RH values not consistent with long-term stability of the beads.

The sensor measures humidity by changes in capacitance. It operates in a similar fashion to the probe level sense board.

5.11 Slave Processor Boot Program

In the IMMULITE 2000/2500, all software used by the Z8 slave processors is downloaded from the control PC and stored in the 32K-byte SRAM. Because of this design,

- o it is never necessary for a service engineer to upgrade microcode
- upgrades to Z8 microcode are made via data transmission through a 1-Kbyte dual-port RAM.

It is the *boot program* that enables software to be changed so easily. Between each Z8 microcontroller in the system and the single-control computer is a 1024-byte dual-port RAM. The boot program resides within this RAM. Although the boot program is very small (approximately 358 bytes), it is very powerful.

How the Boot Program Works

The functionality of the boot program is described in the following paragraphs:

Boot Program Capabilities

Because of its small size, the boot program can provide only three basic functions:

- o checking the Z8 memory
- o loading a 256-byte line of instructions or data into the Z8 SRAM
- o causing the program counter of the Z8 to jump to a specific RAM location and execute code from this location

When the boot program is not performing any of these three functions, it is executing a loop program that causes a diagnostic LED on the slave board to toggle. This provides visual feedback, indicating that the program is operating properly.

On Power Up

- o none of the Z8 microcontrollers are operational
- o no executable code is available
- the RAM area is empty of either instructions or data
- the control computer has direct access to each of the 1K-byte dual-port RAMs in the system

While keeping the reset line of the Z8 low, the control PC fills the dual-port RAM with the boot program. This program occupies Z8 memory locations 000C through 0172 (hexadecimal). The first 12 locations (0000 – 000B) are reserved for interrupt vector addresses. After the boot program is transferred, the Z8 software is reset by bringing the PC reset line high and logically "AND" ing this with PC data bit 0.

On Reset

The Z8 starts executing instructions from location 000C, which is the first location of the boot program in the dual-port RAM. Because the first 12 Z8 memory locations are reserved for interrupt vectors, when it is powered on, the Z8 executes program instructions from the dual-port RAM, rather than from either the ROM or SRAM.

PMT Slave Processor Temperature Control

In addition to motor slave processor boards, the IMMULITE 2000/2500 has a separate Z8 microcontroller-based circuit board. This board is used to

- o control the temperatures of the Substrate, Luminometer, and Tube Processor Heaters
- o count electrical signals from the PMT

This circuit board also

- o forms the core of the high-speed synchronous serial data bus
- o controls the speed of two brushless DC motors
- drives two RS-232 asynchronous data channels
- o distributes additional digital I/O throughout the system via a 40-pin cable

Communication between the control PC and the temperature processor is provided via a 1-Kbyte dual-port RAM, as it is with the motor slaves. Although the design is based on the same microcontroller as that used for the motor slaves, there are considerable differences in the physical design.

Chip Set of the Temperature Control Processor

The core integrated circuits on this board are the following:

- o Zilog A86C93 microcontroller
- o NEC upd71054 16-bit multi-mode counter
- o NED upd71055 port expander
- o LSI7166 24-bit multi-mode counter
- o 74HC4020 binary counter
- o AMD PALCE26V12 PLD
- o Dallas Semiconductor IDT7130 dual-port RAM

The ICs comprising the above list are equivalent to those of the motor slave board. The differences lie in the quantity of chips used and the manner in which they are used. These integrated circuits (ICs) are described below:

o Z8 ADDRESS DECODING—AMD26V12

In order to save parts and to maintain some design simplicity, the same PLD program used to create chip selects and read/write signals is used on the motor slave board. This has been done even though the physical IC selected is different. The decoded address space has been made compatible, as shown on the Z8 memory map.

o PMT COUNTING—LSI7166

IMMULITE 2000/2500 uses a single LIS17166 multi-mode counter to count PMT pulses. The counter chip is configured as a single-input 24-bit counter, which is capable of counting past 16,777,000 before wrapping around to zero. This capability is more than is required to measure the photonic emission from the IMMULITE 2000/2500 test units. The counter is resident on the Z8 8-bit data bus. To use the IC, all that is required is to write to it the correct control word to configure it for straight counting and then to read its output latch three times in succession. Performing this read at regularly spaced intervals produces the number of counts per second.

The output of the PMT is terminated into a 50-Ohm load to reduce the possibility of reflected signals that could cause errors in the count.

o TEMPERATURE CONTROL—upd71054

See Temperature Control information, earlier in this section.

BRUSHLESS DC MOTOR CONTROL

The IMMULITE 2000 uses two brushless DC motors to control the speed of the tube wash station and the sample dilution well. The IMMULITE 2500 uses three brushless DC motors to control the speed of the tube wash station and the sample dilution well. The speed of the motors is proportional to the voltage fed to a pin on the Motorola MC33035 control IC. These ICs are located on the motor driver boards. The voltage used for speed control is converted from digital data. The source of the digital data is the synchronous serial data bus. In addition to the data needed for speed-control voltage, the processor provides I/O lines for enabling, dynamically braking, and fault detection in the two brushless motors.

To measure the speed of the motors, the Hall effect pulses of the motors are fed into a upd71054 16-bit multi-mode counter. This counter resides on the Z8 data bus. To measure the motor speed, the Z8 has only to chip select the counter, read the count registers, and time the average readings. This feedback can be used with the A/D converters to auto-tune the motor speed, thereby eliminating the need for trimpot adjustments.

o RS-232 SERIAL COMMUNICATION—Z86C93

The Z86C93 microcontroller has a built-in RS-232 asynchronous serial communication controller. This circuit board takes advantage of this in the form of two multiplexed communication channels. A 74HCT241 multiplexer is used in conjunction with a MAX232 level shifter to provide the two channels at the proper voltage. The Z8 automatically formats and sets the baud rate of the serial data using an internal timer.

o ADDITIONAL I/O

A single upd71055 I/O port expander is used to create more signal lines than can be provided by a Z8. This IC is resident on the Z8 data bus. A byte of data can be read from or written to an external port over this data bus. All of this additional I/O capacity is distributed to circuit boards via the 40-conductor cable used for the synchronous serial data bus.

Loading a Program into a Slave Processor

The procedure for loading a program into the slave processor is described in the following paragraphs.

While the boot program is executing from the dual-port RAM, it is waiting for a command to be issued from the control PC. The control PC is permitted to write data to specified locations—specifically, 017F through 028F (hexadecimal), as mapped into the Z8 memory—of the dual-port RAM. The control PC is not permitted to read data from these locations; the Z8 is not permitted to write data to these locations.

In order to transfer program instructions or data to a slave's SRAM, the control PC must first load the data into the proper dual-port RAM locations. These locations are as follows:

- The first available location, 017F (hexadecimal), holds a sequence number of a command to be issued to the slave.
- The next two locations, 0180 and 0181 (hex), are filled by the control PC with the high byte and low byte of the Z8 memory location at which the program will be loaded.
- Location 0182 contains the number of bytes to be transferred.
- Location 0183 contains the check sum of the line to be transferred to Z8 memory.
- The control PC can then fill locations 0184 through 028F with the program contents.

When the control PC is finished loading the dual-port RAM with the line of the program to be transferred, it writes the command number into mailbox 03FF. The Z8 is automatically interrupted and checks the data in locations 0182 and 0183 for parity.

- If parity is not met, a message to this effect is sent to the control PC.
- If parity is good, the mailbox is read.

The message in the mailbox is the number of the function to be executed by the Z8. If the message is present, for example, command 0 (zero), the Z8 loads the program instructions from the dual-port RAM into the proper locations of the Z8 SRAM. A 0 (zero) is sent back to the control PC via its mailbox location (03FE), informing it that the command was received and executed.

This procedure continues until all lines of the Z8 program are transferred to its SRAM. When it is time for the Z8 to execute the program loaded into its 32K RAM, the control PC issues a command, instructing the Z8 to begin executing the program from the Z8 location, 8020(h).

5.12 Quadrature Encoders

The IMMULITE 2000/2500 uses encoders to increase the positional accuracy of step motors, enable jam detection, and provide constant positional knowledge about the location of a given axis.

The IMMULITE 2000/2500 uses optical encoders supplied by Hewlett-Packard Corporation. These encoders are economical, easily mounted to the motors used in the system, and easily interfaced electrically.

The step motors used in the IMMULITE 2000/2500 require either 200 or 400 steps per revolution. The encoders used have 400 lines per revolution, making them mathematically integral with the motors.

The encoders produce three, distinct electrical signals:

- o phase A
- o phase B
- o index

Phase A and Phase B signals are counted to determine the position of the motor. Each of these signals produces 400 TTL pulses per encoder revolution. The index signal produces one pulse per revolution and can be used to determine a point of origin for some axes of motion.

Phase A and Phase B have a *quadrature phase relationship*, i.e., they are 90° out of phase from each other. The rising edge of Phase A leads the rising edge of Phase B. This information can be used to determine the motor's direction of motion. If the leading edge of Phase B were to lead that of Phase A, then the direction of motion would have to be reversed.

The three-encoder signals are pulled up to +5V via pull-up resistors located on the motor driver boards. (These boards power the motor to which the encoder is fastened.) These signals are then fed directly to a motor slave processor board. Phases A and B are digitally filtered to assure that the signals are cleaned from electrical noise. The index signal is fed to an I/O port-expander IC.

The quadrature phase signals of each encoder are counted using an LS17166 24-bit multi-mode counter IC. This IC can be configured to interface directly with quadrature encoders. The 24-bit counting capability of this IC allows direct counting of over 16 million encoder pulses before the counter wraps around to zero. This is more than sufficient for application in the IMMULITE 2000/2500.

The counter resides on the Z8 parallel 9-bit data bus, and is enabled via chip selects generated by a PLD. The counter has several control registers to which to write and both a status register and an output register from which to read. Z8 address bit 0 is used to decide whether a register is written to or read from.

A control word from the Z8 is used to configure the counter for quadrature encoder reading. Once this is configured, it is possible to read the contents of the counter from the output latch, one byte at a time, until all 24 bits are read. It is not necessary to read all three bytes of the counter. The low byte of the count is accessed first and, if that is all that needs to be read, then it is not necessary to read the higher-order bytes. This reading occurs between each step signal delivered to each motor in the system. The low-order byte is read from the encoder and compared with a variable in order to determine if a motor jam has occurred.

5.13 Synchronous Serial Data Bus

Throughout the IMMULITE 2000/2500, there is a need to convert digital data to analog voltages and for converting analog voltages to digital data. The uses for such data conversion are listed below:

Analog-to-Digital Data Conversions

- Bead dispenser dry box humidity measurement
- Reagent Carousel temperature
- Luminometer temperature
- Tube processor temperature IMMULITE 2000
- Luminometer temperature IMMULITE 2500
- Incubator temperature IMMULITE 2500
- Substrate temperature
- Substrate container level
- Trigger #1 container level¹
- Trigger #2 container level²
- Distilled water level
- Waste water level
- Used test unit waste level
- o Probe wash container level
- Ambient temperature

Digital-to-Analog Data Conversions

- Control of the dilution well brushless DC motor
- Control of the tube wash brushless DC motor(s)
- Control of the variable-speed van for Instrument cooling

The synchronous serial bus originates on the temperature control processor board. The serial bus, by itself, requires three signal lines. These are the following:

- data in
- data out
- o synchronous serial clock

Four additional signals are used for decoding the addresses of up to 16 devices controlled by the bus. This data is carried to the controlled devices by a 40-conductor cable. The cable is daisy-chained from one circuit board to the next. The remaining conductors of the 40-conductor cable are used to transmit digital data between the temperature processor board and any devices that require control signals.

¹ Trigger 1 is currently unavailable.

² Trigger 2 is currently unavailable.

The data to be transmitted is formatted by the Z8 microcontroller. In general terms, the data is transmitted as follows:

- 1. The address of the device to be selected is sent out over the bus as a parallel nibble of data. The address data is decoded by a 74HCT138, which is present on each serial board carrying a serial device, to create the chip select for the serial IC.
- **2.** When the chip select is present on the IC, the Z8 microcontroller can transmit data both to and from the chip.
- **3.** The Z8 changes the data to be transmitted from a parallel to a serial format, one bit at a time. Output port 2 of the Z8 is treated as a serial register for this purpose.
- **4.** A control word is sent to the converter, telling it to begin a conversion. If there are multiple channels to select, the channel selector is normally sent with the control word. Each serial data bit transmitted to or received from a serial device is clocked into or out of a serial register in the IC. The data is usually transmitted in synchronization with the rising edge of the serial clock. The serial clock is generated by the Z8.
- 5. The conversion starts after the last bit of the control word is received. The converted data is stored by the IDC until it is read out by the Z8. All the A/D converters have a resolution of at least 12 bits. This requires at least two bytes of data to be read from the IC.
- **6.** Reading converted data from the IC is essentially the same as transmitting a control word to it. The device's address is transmitted, creating a unique chip select. With the chip select present, data is shifted out of a serial register in synchronization with the rising edge of the serial clock. The Z8 converts the data from serial to parallel format, then processes it as required.

5.14 Fluid Level Measurement Using Strain Gauges

The IMMULITE 2000/2500 has the following fluid containers:

- One small (250mL) container, which hold the substrate and the two reaction triggers³
- Three large containers, holding the probe wash, distilled water, and waste fluids
- One container which holds bulk waste in the form of used test units

The measurement of the volume of material in these containers is accomplished with strain gauges, operational amplifiers, and analog-to-digital (A/D) converters.

The strain gauge is a resistive bridge that is either fastened to or etched into a beam of metal. This beam is manufactured to deflect under load in a very specific manner. When the beam deflects, the resistive legs of the bridge are unbalanced. The bridge is energized with a constant voltage or current. Under unbalanced conditions, the bridge produces a voltage proportional to the load on the strain gauge beam.

A bottle of substrate or trigger constitutes the load that unbalances the bridge. When a bottle is full, the bridge is unbalanced at its maximum level. As the fluid is used to perform tests, the fluid level drops, which causes the load on the strain gauge to drop, which, in turn, causes the output of the bridge to diminish. This change in strain gauge voltage is the information used to measure the fluid level.

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³ These reaction triggers are currently unavailable.

The sensitivity of the bridge's usable output voltage is small. Therefore, the bridge output must be amplified to a higher level. Each strain gauge in the system has its own differential voltage amplifier. This amplifier not only amplifies the bridge signal but also converts it from a differential to a single-ended output voltage. The amplified signal from each of the seven strain gauges is fed into an 8-channel 12-bit serial A/D converter. A control word, sent over the synchronous serial bus to the A/D converter, selects which input channel is to be converted. The digitized output of the converter is transmitted to the temperature processor board over this serial data bus. The Z8 microcontroller processes the digitized strain gauge data and calculates the volume of fluid present in each container.

Load Cell Calibration

The Load Cell Calibration is performed in the Diagnostic Tester, Special Testing mode. Select "Calibrate Load Cells" button from the Diagnostic Tester screen. Using the volumes designated in the table below, place the required volume, in the appropriate container, on the load cell to be calibrated. Then, "left mouse click" on the corresponding Container Empty/Container Full value to capture the strain gauge feedback value displayed in the "Current Value" box. The box selected should now change to reflect the "Current Value."

LOAD CELL CALIBRATION VALUES

LOAD CELL	FILL VOLUME	EMPTY VOLUME
SUBSTRATE	300 mL	50 mL
TRIGGER 1	N/A	N/A
TRIGGER 2	N/A	N/A
PROBE WASH	2000 mL	200 mL
DISTILLED WATER	5900 mL	1 Liter
LIQUID WASTE	6.750 mL	0
SOLID WASTE	1200 grams	bag only

5.15 The Driver Boards

The IMMULITE 2000 uses 22 stepper motors. The IMMULITE 2500 uses 28 stepper motors. These motors produce electrical noise. In order to reduce the amount of electrical noise produced by the Instrument, the power drivers have to be located as close as possible to the loads they are driving. To do this, it was necessary to design a number of different driver boards. These boards are fastened to the mechanical assemblies that they drive. This creates a modular arrangement for the both the assemblies and the boards that drive them.

All driver boards:

- have separate power connections for +5V, +24V, and, where needed, $\pm 12V$ power supplies
- o use surface-mount components, where applicable, to save space
- o are a minimum of four layers deep for the purpose of
 - keeping electrical noise and interference low
 - isolating electrical regions for power, digital signals, and analog signals from each other

The systems, IMMULITE 2000 and IMMULITE 2500 have the following driver boards:

- Tube Processor front IMMULITE 2000
- Tube Processor rear IMMULITE 2000
- o Reagent Carousel
- o Sample Carousel
- Bead Carousel
- Tube Feeder
- Dual Pipettor
- Digital Fluidics

Some of the boards are small and relatively simple, with only one motor drive and few inputs from sensors. Others are large, with as many as five motor drives, solenoid drivers, and sensor interfacing for multiple axes of motion. Any driver board capable of data conversion is connected to the temperature control slave processor via a 40-conductor cable. This 40-pin cable contains the data path for the synchronous serial data bus.

5.16 Control Board Interface

A slave processor board must control all driver boards. Each driver board contains all the intelligence for controlling motion in the system. Control signals are sent from the slave processors to the driver boards; sensor data is sent from the driver boards to the slave processors. Each driver board has a minimum of one 20-pin connector, which is used to transmit bi-directional data.

The slave processors have the following characteristics:

- Each slave processor is capable of transmitting 72 bits of digital data.
- The data is arranged in a repetitive format of 20 signals.
- Each 20-signal group is required for a single-step motor axis and its associated sensors.
- These 20-signal groups can be gathered into larger bundles of 40, 60, 80, or 100 signals.
- The arrangement of the 20-signal groups is dependent upon the requirements of each driver board.
 - A driver board with only a single-step motor requires a single 20-signal group and a single 20-pin connector.
 - A driver board with five step motors requires five 20-signal groups and, possibly, a 100-pin connector.

The arrangement of a 20-signal group is shown in the following table.

Pin No.	Description
1	Ground
2	Home position
3	Ground
4	Step
5	Ground
6	Enable
7	Direction
8	Hold
9	Ground
10	Encoder A
11	Encoder B
12	Encoder index
13	Ground
14	Ground
15	Input/output
16	Input/output
17	Input/output
18	Input/output
19	Input/output
20	Input/output

The next 20 pins, 21 through 40, repeat the same pattern for the next step motor.

Common Step Motor Drive

The Common Step Motor Drive is described in the following paragraphs.

All step motors on the IMMULITE 2000/2500, except as noted below, use the L297, L298, and L6203 step motor control ICs to translate digital data from the slave processor boards into usable motion.

<u>Note</u>: The Processor Shuttle, Incubator, Wash Stations and Luminometer utilize programmable IMS© Motor/Controller Assemblies. These assemblies house the appropriate driver circuitry. Their signals are received from the appropriate Slave PCB and transferred through the Interface PCB, P/N 450195 to the appropriate Motor.

• The L297 receives digital data from the slave processor The L297 is also used in the IMMULITE

- The L298 is a dual full-bridge power IC, manufactured with bipolar technology. It can supply three amperes of continuous current to a step motor winding.
- The L6203 is a single-bridge power IC that can supply five amperes of continuous power to a step motor winding. The L6203 is manufactured with CMOS transistors.

The L297 receives data from the slave processor. This data—which contains information for motor, current level, enable, and motor step—is translated into the proper format for the sequential excitation of step motor windings. The electrical current, flowing through the motor windings, is sensed with low-value resistors. The voltage developed across the resistors is proportional to this current and it is fed back to the L297. The L297 turns off the current to the motor when it reaches a predetermined threshold, thus maintaining a constant current through the motor winding.

To guarantee accurate positioning of a mechanical assembly, all but two of the axes controlled by step motors use optical encoders. The encoders are rigidly fastened to the body of the motor. Each encoder has three channels. Two of the channels produce a quadrature signal pattern, 90° out of phase, which is counted to determine how far the axis has translated. The third channel is an index that produces a signal each time the encoder rotates 360°.

To locate the point of origin of motion, each axis has an associated home-position sensor. These home-position sensors are connected directly to the I/O ports of the Z8 processor so that they can be sensed as quickly as possible.

Additional Functions of the Driver Boards

In addition to driving the step motors, the Driver Boards do the following:

- Form the interface for all sensors used to monitor mechanical position
- Contain the control and power ICs used to control brushless DC motors
- Hold the discrete power devices used to drive solenoid pumps
- Are mounted with many of the A/D and D/A converters used in the system

Motor Slave Chip Set

The integrated circuits of the motor slave processor boards are the following:

- o Zilog Z86C93 microcontroller
- o NEC upd71054 16-bit multi-mode counter
- NEC upd71055 port expander
- o LSI 7166 24-bit encoder counter
- o Motorola MC14490 digital filter
- o AMD PALCE26V12 PLD
- o 74HC4020 binary counter
- o Dallas Semiconductor IDT7130 Dual-Port RAM

Each of these boards is described in the following paragraphs.

Z86C93

The Zilog Z86C93 is an 8-data bit and 16 address bit microcontroller with the following characteristics:

- runs at a crystal frequency of 20 MHz with an internal clock rate of 10MHz or 100nsec. An average instruction of 10 clock cycles takes 1µsec to execute
- has four 8-bit output ports, two of which are dedicated to address and data buses; the other two ports are user-configurable and can be used for I/O, RS232 serial communication, or external interrupts
- o has 256 internal registers
- has three counter timers
- has multiplication and division functions

On the slave processor, the Z8 microcontroller is used to perform the following functions:

- Along with the upd71054 timer IC, it is used to simultaneously control five step motors at a maximum rate of 5000 steps per second.
- Along with the upd71055 port expander, it is used to control 48 digital I/O lines.

Program instructions are executed from a 32-Kbyte SRAM. The source code for the processor is written in Z8 assembler language. It is transmitted to the Z8 from the control PC through the 1-Kbyte dual-port RAM. The Z9 reads the program instructions from the dual-port RAM and stores them in its SRAM.

NEC upd71054

This IC contains three general-purpose 16-bit counters/timers. These devices can be programmed independently of each other to provide between one and five different operating modes. Writing an 8-bit word to an internal control register configures the chip.

On the motor slave processor, the 71054 is configured as three, independent binary counters, each of which is used to count the amount of time spent between step pulses sent to a motor. For a time base, the 71054 uses a divided-down clock signal, derived from the 20MHz crystal. An initial 16-bit count value is written to a counter by the Z8 processor over its 8-bit data bus. On each tick of the clock, the counter is decrements by one. At the end of the count, the OUT pin of the counter changes state. This output is connected to an external interrupt on the Z8. When the Z8 senses this interrupt, it "knows" it is time to step a motor and to write another value to the timer. If the 16-bit count value written to the timer is changed from the previous count, the time between motor steps will vary. This method is used to set the velocity and acceleration of a step motor.

NEC upd71055

This IC is an I/O (input/output) port expander, which is connected to the Z8 data bus and which occupies four locations on the Z8 memory map. The highest location of the device is an internal control register that is used to configure the order of the ports. The other three locations are registers that represent the ports themselves. When these registers are written to, they represent the data present at an input port. Placing the correct address on the Z8 address bus accesses a register of this device. A chip select is decoded by the PLD, the processor produces read or write signals, and data is read into or out of the Z8.

Two port-expansion chips are available for each Z8 slave processor, enabling the processor to control 48 digital I/O signals beyond the 16 digital I/O signals it contains. The Z8 uses the I/O ports to turn on devices such as solenoids and AC motors and to read the state of sensors.

LS17166

This device is a 24-bit multi-mode counter. Its purpose on the motor slave processor boards is to count the pulses produced by the quadrature encoders, which are fastened to most of the step motors in the system. This device is connected directly to the Z8 data bus and occupies two locations in the Z8 memory map. One location is used to write to the internal control registers, which are used to configure the counter and to direct its dynamic operation.

The internal control registers consist of the following:

- o master control register
- o input control register
- o output control register
- o quadrature register

The read register accesses the output latch, which contains the data to be read from the counter. The counter stores 24 bits of data. The output register must be read three times.

For purposes of motor control, this device is set up to perform quadrature counting of the encoder pulses. Each motor slave board has 10 LSI1766s—one for each motor controlled by the two Z8s located on the board.

MC14490

The Motorola MC14490 is a multiple-input digital filter, which is used to assure that the encoder pulses from the step motors are clean. A clock signal, needed by the chip, is derived from the divided-down 20MHz crystal frequency. The input signal from the encoder is passed through a 4-bit shift register that is clocked by this divided-down crystal frequency.

AMD PALCE26V12

This programmable logic device (PLD) is used by the motor slave board to provide the Z8 with a number of output signals required to control its support chips. Internally, the PLD consists of an array of AND/OR gates connected to fusible links. The device is programmed by writing Boolean algebraic statements in sum-of-products form. Terms for the Boolean statements are derived from the input signals to the PLD.

For the IMMULITE 2000/2500 motor slave, input signals to the PLD consist of the following:

- o the Z8 read/write line
- a data strobe
- **o** the following address lines:
 - ZA1 through ZA4
 - ZA10
 - ZA15

The outputs derived from these inputs are all the chip selects necessary for all peripheral ICs used by the Z8 and by separate read and write lines. One PLD is available to each Z8 for address decoding.

74HC4020

This is a 12-stage binary counter, which is used to divide down the 20 MHz crystal frequency to lower clock rates. The lower frequencies—used by the 71054 timers and the MC14490 digital filters—are selectable through jumpers.

IDT7130

This is a 1024-Byte dual-port RAM. All RAM locations are accessible from two discrete ports. When data is written to the two highest locations in the DPRAM, 3FE and 3FF, interrupt lines are set. These interrupt lines can be used to notify a host processor that a message is pending. When the data is read from these locations, the interrupt lines are reset. The dual-port RAM is used as a medium for interprocessor communications.

Chapter 6: New BIOS Settings

6.1 Introduction

This section incorporates the BIOS Settings for the ATX Style Chassis ranging from serial number D0404 through the current serial number range.

Note: Please note Instrument serial number to ensure the proper BIOS is used.

901896 or 902141, Motherboard, Intel SE440BX2, for User Side S/N D0404 – F1525

Enter the BIOS Configuration Menu.

The following instructions must be performed to correctly configure the Pentium Motherboards.

Main Menu

Main	Advanced	Security	Power	Boot	Exit
	BIOS Version		4S4EB2X0.86A.0022.P15		
	Processor Type Processor Speed Cache RAM System Memory Memory Bank 0 Memory Bank 1 Memory Bank 2		Pentium III XXX MHz XXX KB 128 MB 128 MB SDRAM 0 MB 0 MB		
	Language ECC Configuration L2 Cache ECC Support			[English (L	JS)]
				[ECC] [Enabled]	
	System Time System Date			[00:00:00] [MM/DD/YY]	

BIOS Versions will vary, and the above is for example only.

Set the correct date and time.

Verify the processor speed, and system memory.

Move to the Advanced selection from the BIOS menu.

Main Advanced Security Power Boot Exit

Setup Warning

Setting items on this menu to incorrect values may cause your system to malfunction.

Plug & Play O/S: [No] Reset Configuration Data: [No]

Numlock: [Auto]

Peripheral Configuration IDE Configuration Floppy Options DMI Event Logging Video Configuration Resource Configuration

Set the Plug & Play O/S to No.

Set Numlock to Auto.

Highlight Peripheral Configuration and press ENTER.

The following screen will be displayed:

Main Advanced Security Power Boot Exit

Serial port A: [Auto]
Serial port B: [Disabled]
Parallel port: [Auto]

Mode: [Bi-directional]

Audio: [Enabled]
Legacy USB Support: [Disabled]

Make sure settings match the above menu window, make any necessary changes.

Press ESC to return to the Advanced menu.

Tab down to IDE Configuration and press ENTER.

The following screen will be displayed:

Main Advanced Security Power Boot Exit

IDE controller: [Both]
Hard Disk Pre-Delay [Disabled]

Primary IDE Master [WDCXXXXXXX]

Primary IDE Slave [None]

Secondary IDE Master [CD-56E – (SM)]

Secondary IDE Slave [None]

Make sure settings match the above menu window, make any necessary changes. Press ESC to return to the Advanced menu.

Tab down to Floppy Options and press ENTER.

The following screen will be displayed.

Main Advanced Security Power Boot Exit

Floppy disk controller: [Enabled]

Diskette A: [1.44/1.25 MB 3.5"]

Floppy Write Protect: [Disabled]

Make sure settings match the above menu window, make any necessary changes.

Press ESC to return to the Advanced menu.

Tab down to DMI Event Logging and press ENTER.

The following screen will be displayed.

Main Advanced Security Power Boot Exit

Event log capacity Space Available

Event log validity Valid

View DMI event log [Enter]

Clear all DMI event logs [No]

Event Logging [Disabled]
Ecc Event Logging [Disable]
Mark DMI events as read [Enter]

Make sure settings match the above menu window, make any necessary changes.

Press ESC to return to the Advanced menu.

Tab down to Video Configuration and press ENTER.

The following screen will be displayed:

Main Advanced Security Power Boot Exit

Palette Snooping: [Disabled]

AG:P Aperture Size: [64 MB]

Default Primary Video Adapter [AGP]

Make sure settings match the above menu window, make any necessary changes.

Press ESC to return to the Advanced menu.

Tab down to Resource Configuration and press ENTER.

The following screen will be displayed:

Main	Advanced	Security	Power	Boot	Exit	
	C800 – CBFF:		[Av	vailable]		
	CC00 – CFFF:		[Available]			
	D000 – D3FF:		[Available]			
	D400 – D7FF:		[Av	vailable]		
	D000 – D8FF:			[Available]		
	DC00 – DFFF:		[Av	vailable]		
	IRQ 3:		[Av	vailable]		
	IRQ 4:		[Av	vailable]		
	IRQ 5:		[Av	vailable]		
	IRQ 7:		[Av	/ailable]		
	IRQ 10:		[Av	vailable]		
	IRQ 11:		[Av	vailable]		

All resources must be "Available," make necessary changes.

Press ESC to return to the Advanced menu.

Tab over to Security.

The following screen will be displayed:

Main Advanced Security Power Boot Exit

User Password Is: Clear Administrator Password Is: Clear

Set User Password [Enter]
Set Administrative Password [Enter]

User Setup Access: [View Only]

Unattended Start [Disabled]

Settings should be a close match to the above menu window, make necessary changes.

Tab over to Power.

The following screen will be displayed:

Main Advanced Security Power Boot Exit

Power management: [Disabled]

Make sure settings match the above menu window, make any necessary changes.

Tab over to Boot.

The following screen will be displayed:

Main Advanced Security Power Boot Exit

Boot-time Diagnostic Screen [Enabled]
QuickBoot Mode: [Disabled]
Scan User Flash Area: [Disabled]

After Power Failure: [Last State]
On Modem Ring: [Power On]
On LAN: [Power On]
On PME: [Stay Off]

First Boot Device [Hard Drive]

Second Boot Device [Removable Devices]
Third Boot Device [ATAPI CD-ROM Drive]

Fourth Boot Device [Network Boot]

Hard Drive

Removable Devices

Make sure settings match the above menu window, make any necessary changes. Tab over to Exit.

The following screen will be displayed:

Main Advanced Security Power **Boot** Exit Exit Saving Changes [Enter] Exit Discarding Changes [Enter] Load Setup Defaults [Enter] **Load Custom Defaults** [Enter] Save Custom Defaults [Enter] **Discard Changes** [Enter]

Highlight Exit Saving Changes, and press ENTER when asked to save the changes.

You will receive a message that the pins on the Configuration jumper should now be set to "Normal", and the system can now be powered down.

Power down the system.

Remove the On/Off switch placed on the power on pins located in the front panel connector.

Configuration is complete.

902204, Motherboard, Intel 815EEA2LU for User Side S/N F1568 – F1572, F1616 and higher

Enter the BIOS Configuration Menu.

The following instructions must be performed to correctly configure the Motherboards.

Main Menu

Main	Advanced	Security	Power	Boot	Exit
	BIOS V	ersion		EA81520A.	86A.0017.P11
	Processo		Intel Pentiu	m III	
	Processor Speed			XXX MHz	
	System Bus Frequency			XXX MHz	
	Cache RAM			256 KB	

Total Memory XXX MB

Memory Bank 0 XXX MB SDRAM

Memory Bank 1 Not Installed

Memory Bank 2 Not Installed

Language [English]

Processor Serial Number [Disabled]

System Time [00:00:00]

System Date [MM/DD/YY]

BIOS Versions will vary, and the above is for example only.

Set the correct date and time.

Verify the processor and system memory.

Move to the Advanced selection from the BIOS menu.

The following screen will be displayed:

Setup Warning

Setting items on this menu to incorrect values may cause your system to malfunction!

Extended Configuration [Not Used]

PCI Configuration

Boot Configuration

Peripheral Configuration

IDE Configuration

Diskette Configuration

Event Log Logging

Video Configuration

Highlight PCI Configuration and press ENTER.

The following screen will be displayed:

PCI Slot 1 IRQ Priority [Auto]
PCI Slot 2 IRQ Priority [Auto]
PCI Slot 3 IRQ Priority [Auto]
PCI Slot 4 IRQ Priority [Auto]

PCI Slot 5 IRQ Priority [Auto]

Make sure settings match the above menu window, make any necessary changes.

Press ESC to return to the Advanced Menu.

Highlight Boot Configuration and press ENTER

The following screen will be displayed:

Plug & Play O/S [No]
Reset Configuration Data [No]
Numlock [On]

Make sure settings match the above menu window, make any necessary changes.

Press ESC to return to the Advanced Menu.

Highlight Peripheral Configuration and press ENTER

The following screen will be displayed:

Serial Port A [Auto]
Serial Port B [Auto]
Parallel Port [Auto]

Mode [Bi-directional]

Audio Device [Enabled]

Lan Device [Enabled]

Legacy USB Support [Enabled]

Make sure settings match the above menu window, make any necessary changes.

Press ESC to return to the Advanced Menu.

Highlight IDE Configuration and press ENTER

The following screen will be displayed:

IDE Controller [Both]

Hard Disk Pre Delay [Disabled]

Primary IDE Master [XXXXXXXX]

Primary IDE Slave [Not Installed]

Secondary IDE Master [CD ROM XXX]

Secondary IDE Slave [Not Installed]

Highlight each IDE 1 at a time and select ENTER

Type [Auto]

All other settings should be grayed out. Press ESC to return to the Advanced Menu.

Highlight Diskette Configuration and press ENTER

The following screen will be displayed:

Diskette Controller [Enabled]

Floppy A [1.44/1.25 MB 3 ½]

Diskette Write Protect [Disabled]

Press ESC to return to the Advanced Menu.

Highlight Event Log Configuration and press ENTER

The following screen will be displayed:

Event Log [Space Available]

Event Log Validity [Valid]

View Event Log

Clear All Event Logs [No]

Event Logging [Enabled]

Mark Events as Read

Press ESC to return to the Advanced Menu.

Highlight Video Configuration and press ENTER

The following screen will be displayed:

Primary Video Adapter [AGP]

AGP Hardware Detected Integrated

<u>Note</u>: The actual performance of the video hardware is dependant upon the operating system and video drivers.

Press ESC to return to the Advanced Menu.

Skip Security and do NOT make changes.

Highlight Power and press ENTER

Highlight APM and press ENTER

The following screen will be displayed:

Power Management [Disabled]

Inactivity Timer [20 Minutes](Grayed out)

Hard Drive [Enabled] (Grayed out)

Press ESC to return to the Power Menu

Highlight ACPI and press ENTER

The following screen will be displayed:

ACPI Suspend State [S1 State]

Video Repost [Disabled]

Wake on Lan from S5 [Stay Off]

Press ESC to return to the Power Menu

The following screen will be displayed:

After Power Failure

[Last State]

The options below are not related to ACPI and may be ignored when shutting down using an ACPI OS.

Wake On PME [Stay Off]

Wake On Modem Ring [Stay Off]

Highlight BOOT and press ENTER

The following screen will be displayed:

Quiet Boot [Disabled]

Intel ® Rapid BIOS Boot [Disabled]

Scan User Flash Area [Disabled]

Highlight Boot Device Priority and press ENTER

The following screen will be displayed:

1st Boot Device [Removable Device]

2nd Boot Device [Hard Drive]

3rd Boot Device [Disabled]

Press ESC to return to the Boot Menu

Highlight Removable Devices and press Enter

The following screen will be displayed:

1st Removable Device [1st Floppy]

Press ESC to return to the Boot Menu

Highlight ATAPI CD-ROM Drives and press ENTER

The following screen will be displayed:

1st ATAPI CDROM [XXXXXXX]

Press ESC to return to the Boot Menu

Highlight EXIT and press ENTER

Highlight Exit Saving Changes, and press ENTER when asked to save the changes.

You will receive a message that the pins on the Configuration jumper should now be set to "Normal", and the system can now be powered down.

Configuration is complete

<u>Pro-X Style Motherboard, User Side</u> <u>S/N H2643 – J3730</u>

Advanced	BIOS	Features:

Virus Warning [Disable] **CPU Internal Cache** [Enable] External Cache [Enable] CPU L2 Cache ECC Checking [Enable] **Processor Number Feature** [Enable] First Boot Device [Floppy] Second Boot Device [HDD-0] Third Boot Device [CD-ROM] **Boot Other Device** [Enable] Swap Floppy Drive [Disable] Boot Up NumLock Status [OFF] Boot Up Floppy Seek [Enable] Gate A20 Option [Fast] Typematic Rate Setting [Disable] Typematic Rate (Chars/Sec) 6 Typematic Delay (Msec) 250 Security option [setup] OS Select for DRAM > 64MB [non-OS2] Report No FDD for Win 95 [NO] Small Logo (EPA) Show [Disable]

Advanced Chipset Features:

SDRAM CAS Latency Time [2] SDRAM Cycle Time Tras/Trc [Auto] SDRAM RAS To CAS Delay [Auto] SDRAM RAS Precharge Time [Auto] System BIOS Cacheable [Disabled] Video BIOS Cacheable [Disabled] Memory Hole At 15M-16M [Disabled] **CPU Latency Timer** [Enable] **Delayed Transaction** [Enable] AGP Graphics Aperture Size [64MB] Display Cache Frequency [100MHz] On-Chip Video Window Size [64MB]

Onboard Display Cache Setting

CAS# Latency [2]
Paging Mode Control [Open]

RAS to CAS Override [By CAS# LT]

RAS# Timing [Fast]
RAS# Precharge Timing [Fast]

I/O Channel Check NMI [Disabled]

Integrated Peripherals:

On Chip Primary PCI IDE [Enable] On Chip Secondary PCI IDE [Enable] **IDE Primary Master PIO** [Auto] **IDE Primary Slave PIO** [Auto] **IDE Secondary Master PIO** [Auto] **IDE Secondary Slave PIO** [Auto] **IDE Primary Master UDMA** [Auto] **IDE Primary Slave UDMA** [Auto] IDE Secondary Master UDMA [Auto] **IDE Secondary Slave UDMA** [Auto] USB Controller [Enable] **USB** Keyboard Support [Disable] **USB** Mouse Support [Disable] Init Display First [PCI Slot] AC97 Audio [Auto] IDE HDD Block mode [Enable] Onboard FDC Controller [Enable] Onboard Serial Port 1 [3F8/IRQ4] Onboard serial Port 2 [2F8/IRQ3] UART Mode Select [Normal] UR2 Duplex Mode [Half] Onboard Parallel Port [378/IRQ7] [SPP] Parallel Port Mode ECP Mode Use DMA [3] PWRON after PWR-fail [On] Onboard Serial Port 3 [3E8H] Serial Port 3 Use IRQ [IRQ10] [2E8H] Onboard Serial Port 4 Serial Port 4 Use IRQ [IRQ11] Onboard Parallel Port 2 [OFF] Parallel Port 2 use IRQ [IRQ5] Parallel Port 2 Mode [ECP] LPT2 ECP Mode Use DMA [3]

Power Management Setup:

ACPI Function [Disable]
ACPI Suspend Type [S3]

Power Management [User Define]
Video Off Method [DPMS]

Video Off in Suspend [Yes]

Suspend Type [Stop Grant]

MODEM Use IRQ [NA]
Suspend Mode [Disabled]
HDD Power Down [Disabled]

Soft off by PWR BTTN [Instant off]
Wake Up by PCI card [Disable]
Power On by Ring [Enable]
USB KB Wake up from S3 [Disabled]
Resume by Alarm [Disabled]

** Reload Global Timer Events **

Primary IDE 0 [Disable]
Primary IDE 1 [Disabled]
Secondary IDE 0 [Disabled]
Secondary IDE 1 [Disabled]
FDD,COM, LPT Port [Disabled]
PCI PIRQ[A-D]# [Disabled]

PnP/PCI Configuration:

PNP OS Installed [Off]
Reset Configuration Data [Disable]

Resources Controlled by [Auto(ESCD)]
IRQ Resources Press Enter
DMA Resources Press Enter

PCI/VGA Palette Snoop [Disabled]

903975, Motherboard, Pro-X 1750, USER SIDE

S/N J3731-J3735, J3762 and Higher

Advanced BIOS Features:

Virus Warning [Disable] CPU L1 & L2 Cache [Enable] Ouick Power On Self Test [Enable] First Boot Device [Floppy] [HDD-0] Second Boot Device Third Boot Device [CD-ROM] **Boot Other Device** [Enable] Swap Floppy Drive [Disable] Boot Up Floppy Seek [Enable] Boot Up NumLock Status [ON] Gate A20 Option [Fast] Typematic Rate Setting [Disable] Typematic Rate (Chars/Sec) 6 Typematic Delay (Msec) 250 Security option [setup] APIC Mode [Enable] MPS Version Control for OS [1.4]OS Select for DRAM > 64MB [non-OS2]

HDD SMART Capability	[Disable]
Small Logo (EPA) Show	[Disable]

Advanced Chipset Features:

DRAM Timing Selectable	[By SPD]
DRAM CAS Latency Time	[2]
CAS Latency Time	[Auto]
DRAM RAS To CAS Delay	[Auto]
DRAM RAS Precharge Time	[Auto]
Turbo Mode	[Disabled]
Memory Frequency For	[Auto]
System BIOS Cacheable	[Disabled]
Video BIOS Cacheable	[Disabled]
Memory Hole At 15M-16M	[Disabled]
Delayed Transaction	[Enable]
AGP Graphics Aperture Size	[64MB]

On-Chip VGA Setting

On-Chip VGA [Enabled] On-Chip Frame Buffer Size [8MB] I/O Channel Check NMI [Disabled]

Integrated Peripherals:

On Chip Primary PCI IDE IDE Primary Master PIO IDE Primary Slave PIO IDE Primary Master UDMA IDE Primary Slave UDMA	[Enable] [Auto] [Auto] [Auto] [Auto]
On Chip Secondary PCI IDE	[Enable]
IDE Secondary Master PIO	[Auto]
IDE Secondary Master UDMA	[Auto]
IDE Secondary Master UDMA IDE Secondary Slave UDMA	[Auto] [Auto]
USB Controller	[Enable]
USB 2.0 Controller	[Enable]
USB Keyboard Support	[Disable]
USB Mouse Support	[Disable]
AC97 Audio	[Auto]
Onboard LAN	[Enable]
Init Display First	[PCI Slot]
BIOS Flash Function	[Enabled]
IDE HDD Block mode	[Enable]
Power On Function	[button Only]
KB Power On Password	Enter

Hot Key Power On Ctrl-F1 Onboard FDC Controller [Enable] Onboard Serial Port 1 [3F8/IRQ4] Onboard serial Port 2 [2F8/IRQ3] **UART Mode Select** [Normal] Hi, Lo RxD, TxD Active IR Transmission Delay Enabled UR2 Duplex Mode Half

Use IR Pins IR-Rx2Tx2 Onboard Parallel Port [378/IRQ7] Parallel Port Mode [SPP] **EPP1.7 EPP Mode Select** ECP Mode Use DMA [3] PWRON after PWR-fail [On] Onboard Serial Port 3 [Disable] Serial Port 3 Use IRQ [IRQ10] Onboard Serial Port 4 [Disable] Serial Port 4 Use IRQ [IRQ11]

Power Management Setup:

ACPI Function [Enabled]
Power Management [User Define]

MODEM Use IRQ [NA]
Suspend Mode [Disabled]
Soft off by PWR BTTN [Instant off]
Wake Up by PCI card [Disable]
Wake Up on LAN [Disable]
Resume by Alarm [Disabled]

Date (of Month) Alarm 0
Time (hh:mm:ss) Alarm 0:0:0

**Reload Global Timer Events **

Primary IDE 0 [Disabled]
Primary IDE 1 [Disabled]
Secondary IDE 0 [Disabled]
Secondary IDE 1 [Disabled]
FDD,COM, LPT Port [Disabled]

PnP/PCI Configuration:

PNP OS Installed [No]
Reset Configuration Data [Disable]

Resources Controlled by [Auto(ESCD)]
IRQ Resources Press Enter
DMA Resources Press Enter
PCI/VGA Palette Snoop [Disabled]

901904, Tekknor Single Board Computer for Control Side S/N D0404 – F1525

Immediately hit the DEL key to enter the system BIOS.

Under the Setup window select the "Standard" Icon (using the arrow keys) and press ENTER.

Under the Standard Setup window select the "Pri Master" Icon (using the arrow keys) and press ENTER.

Match the Primary Master Hard Disk window to the following settings:

Type : Auto
LBA/Large Mode : On
Block Mode : On
32Bit Mode : Off
PIO Mode : 4

For BIOS Setting on Hard Drives larger than 8 GB, follow SBC BIOS Setting Procedure 600289, otherwise:

Place the Highlight bar on "Type" and press ENTER. Under the Hard Disk Types window select "Auto" and press ENTER. The system will now auto detect the hard drive.

The Auto Detection Status should read as follows:

(MB)	Type	Cyl	Hd	WP	Sec	Size
	Auto	16383	15	65535	63	7560

Select OK (by pressing ENTER) to continue.

From the Primary Master Hard Disk window use the ESC key to return to the Standard Setup window.

Under the Standard Setup window select the "Pri Slave" Icon (using the arrow keys) and press ENTER.

Match the Primary Slave Hard Disk window to the following settings:

Type : Not Installed

LBA/Large Mode : Off

Block Mode : Off

32Bit Mode : Off

PIO Mode : Auto

Use the ESC key to return to the Standard Setup window.

Under the Standard Setup window select the "Sec Master" Icon (using the arrow keys) and press ENTER.

Match the Secondary Master Hard Disk window to the following settings:

Type : Not Installed

LBA/Large Mode : Off

Block Mode : Off

32Bit Mode : Off

PIO Mode : Auto

Use the ESC key to return to the Standard Setup window.

Under the Standard Setup window select the "Sec Slave" Icon (using the arrow keys) and press ENTER.

Match the Secondary Slave Hard Disk window to the following settings:

Type : Not Installed

LBA/Large Mode : Off

Block Mode : Off

32Bit Mode : Off

PIO Mode : Auto

Use the ESC key to return to the Standard Setup window.

Under the Standard Setup window select the "Date/Time" Icon (using the arrow keys) and press ENTER.

Set the date and time (using the arrow keys and +/- keys).

Press ENTER to return to the Standard Setup window.

Under the Standard Setup window select the "Floppy A" Icon (using the arrow keys).

Select "Not Installed" and press ENTER.

Select the option: 1.44 MB 3½

Press ENTER to return to the Standard Setup window.

Under the Standard Setup window select the "Floppy B" Icon (using the arrow keys) and press ENTER.

Select the option: Not Installed

Press ENTER to return to the Standard Setup window.

Press the ESC key to exit the Standard Setup window.

Under the Setup window select the "Advanced" Icon (using the arrow keys) and press ENTER.

Match the Advanced Setup window to the following settings:

Quick Boot : Enabled

Bootup Sequence : C:, A:, CDROM

BootUp CPU Speed : High

BootUp Num-Lock : ON

Floppy Drive Swap : Disabled
Floppy Drive Seek : Disabled
Mouse Support : Disabled

Typematic Rate : Fast

Primary Display : VGA/EGA

Password Check : Setup

Parity Check : Disabled

OS/2 Compatible Mode : Disabled

Wait for 'F1' If Error : Enabled

Hit 'DEL' Message Display : Enabled

Internal Cache : WriteThru

Video C000, 32k Shadow : Enabled

C800, 16k Shadow : Disabled

CC00, 16k Shadow : Disabled

D000, 16k Shadow : Disabled

D400, 16k Shadow : Disabled

D800, 16k Shadow : Disabled

DC00, 16k Shadow : Disabled

Press the ESC key to exit the Advanced Setup window.

Under the Setup window select the "Chipset" Icon (using the arrow keys) and press ENTER.

Match the Chipset Setup window to the following:

DRAM Wait States : 1 Wait

SYSCLK Divisor Select : Auto

AT Ready Delay Selects : No Delay

Back to Back IO Delay : 0 SYSCLK

ISA Refresh : Disabled

Turbo IDE Function : Enabled

Onboard IDE Command Width : 9HS1XCLK

Onboard IDE Back to Back Delay : 16HS1XCLK

Press the ESC key to exit the Chipset Setup window.

Under the Setup window select the "Power Mgmt" Icon (using the arrow keys) and press ENTER.

Match the Power Management Setup window to the following:

Power Management/APM : Disabled

Doze Mode Time Out : 4 sec

Sleep Mode Time Out : 1 min.

Hard Disk Time Out : Disabled

Video Standby Time Out : Disabled

Suspend Time Out : 5 min.

Resume with Modem Ring : Disabled

Suspend Warning Beeps : Enabled

Press the ESC key to exit the Power Management Setup window.

Under the Setup window select the "PCI/PnP" Icon (using the arrow keys) and press ENTER.

Match the PCI/PnP Setup window to the following:

Plug and Play Aware O/S : No

IRQ3 : PnP

IRQ4 : PnP

IRQ5 : ISA

IRQ7 : ISA

IRQ9 : PnP

IRQ10 : ISA

IRQ11 : ISA

IRQ14 : PnP

IRQ15 : ISA

Reserved Memory Size : 64k

Reserved Memory Address : D0000

Press the ESC key to exit the PCI/PnP Setup window.

Under the Setup window select the "Peripheral" Icon (using the arrow keys) and press ENTER.

Match the Peripheral Setup window to the following:

Onboard IDE : Primary

Onboard FDC : Disabled

Onboard Serial Port 1 : 3F8h

Onboard Serial Port 2 : 2F8h

Onboard Parallel Port : Disabled

Parallel Port IRQ : Auto

Parallel Port Mode : Bi-Dir

Parallel Port DMA Channel : None

Press the ESC key to exit the Peripheral Setup window.

Press the Esc key once more to exit the System BIOS.

From the Exit Setup window select the option "Save changes and Exit" then press ENTER, and turn the fixture off.

Configuration is complete.

AAEON Style Motherboard, Control Side S/N F1526 – F1530, F1541 and higher

Immediately select the DEL key to enter the BIOS.

Match the following settings with the SBC BIOS.

Standard CMOS Setup:

Date = Current Date
Time = Current Time

Drive C: Auto
Drive D: None
Drive A: None
Drive B: None
LCD & CRT: CRT

Panel: 640 X 480 Mono Halt On: All, But Disk/Key

BIOS Features Setup:

Virus Warning: Disabled CPU Internal Cache: Enabled External Cache: Disabled Quick Power On Self Test: Disabled Boot From LAN First: Disabled **Boot Sequence:** C Only Swap Floppy Drive: Disabled Boot Up Floppy Seek: Enabled Boot Up NumLock Status: On Gate A20 Option: Fast Typematic Rate Setting: Disabled

Typematic Rate (Chars/Sec):

Typematic Delay (M Sec):

Security Option:

PCI/VGA Palette Snoop:

OS Select for DRAM > 64 MB:

Report No FDD for Win 95:

No

6

250

Setup

Disabled

Non-OS2

Video BIOS Shadowed: Enabled C8000-C8FFFF Shadowed: Disabled CC000-CFFFF Shadowed: Disabled D0000-D3FFF Shadowed: Disabled D4000-D7FFF Shadowed: Disabled D8000-D8FFF Shadowed: Disabled DC000-DFFFF Shadowed: Disabled DC000-DFFFF Shadowed: Disabled

Chipset Features Setup:

Auto Configuration: Enabled L2 (WB) Tag Bit Length: 8 Bits SRAM Back-to-Back: Enabled NA # Enable: Enabled Starting Point of Paging: 1T Refresh Cycle Time (US): 187.2 RAS Pulse Width Refresh: 6T RAS Precharge Time: 4T RAS to CAS Delay: 4T CAS # Pulse Width (FP): 2TCAS # Pulse Width (EDO): 1T 3T RAMW # Assertion Timing: CAS Precharge Time (FP): 1T/2T CAS Precharge Time (EDO): 1T/2TEnhanced Memory Write: Disabled Read Prefetch Memory RD: Enabled CPU to PCI Post Write: 3T

CPU to Burst Memory Write: Disabled ISA Bus Clock Frequency: PCI CLK/4

System BIOS Cacheable: Enabled
Video BIOS Cacheable: Enabled
Memory Hole at 15M-16M: Disabled
CPU Warning Temperature: Disabled

Power Management:

Power Management: Disabled PM Control by APM: Yes

Video Off Option:Susp, Stby→OffVideo Off Method:DPMS Supported

Doze Speed (Div by): 2 Stdby Speed (Div by): 3 MODEM Use IRQ: 3

Hot Key Suspend: Disabled

PM Timers:

HDD Off After: Disabled
Doze Mode: Disabled
Standby Mode: Disabled
Suspend Mode: Disabled

PM Events:

Com Ports Activity: Enabled LPT Ports Activity: Enabled HDD Ports Activity: Enabled

Disabled VGA Activity: IRQ 3 (COM 2): Enabled IRQ 4 (COM 1): Enabled IRQ 5 (LPT 2): Enabled IRQ 6 (Floppy Disk): Enabled IRQ 7 (LPT 1): Enabled IRQ 8 (RTC Alarm): Enabled IRQ 9 (IRQ2 Redir): Enabled IRQ 10 (Reserved): Enabled IRQ 11 (Reserved): Enabled IRQ 12 (PS/2 Mouse): Enabled IRQ 13 (Coprocessor): Enabled IRQ 14 (Hard Disk): Enabled IRQ 15 (Reserved): Enabled

PNP/PCI Configuration:

PNP OS Installed: No Resources Controlled By: Manual Reset Configuration Data: Disabled IRQ-3 assigned to: Legacy IRQ-4 assigned to: Legacy IRQ-5 assigned to: Legacy ISA IRQ-7 assigned to: Legacy ISA IRQ-9 assigned to: PCI/ISA PNP IRQ-10 assigned to: Legacy ISA IRQ-11 assigned to: Legacy ISA IRQ-12 assigned to: Legacy ISA IRQ-14 assigned to: PCI/ISA PNP IRQ-15 assigned to: Legacy ISA DMA-0 assigned to: PCI/ISA PNP DMA-1 assigned to: PCI/ISA PNP DMA-3 assigned to: PCI/ISA PNP DMA-5 assigned to: PCI/ISA PNP DMA-6 assigned to: PCI/ISA PNP DMA-7 assigned to: PCI/ISA PNP

PCI IRQ Activated By: Level PCI IDE IRQ Map To: PCI-Auto

Primary IDE INT #: A

Integrated Peripherals:

Internal PCI/IDE: Primary IDE Primary Master PIO: Auto IDE Primary Slave PIO: Auto Primary Master Ultra DMA: Auto Primary Slave Ultra DMA: Auto IDE Burst Mode: Enabled IDE Data Port Post Write: Enabled IDE HDD Block Mode: Enabled

Onboard FDD Controller: Enabled
Onboard Serial Port 1: 3F8/IRQ 4
Onboard Serial Port 2: 2F8/IRQ 3
UART 2 Mode: Standard

Onboard Parallel Port: Disabled PS/2 Mouse Function: Disabled USB Controller: Disabled From the Main menu select save and exit setup.

Configuration is complete.

Pro-X Style Motherboard, Control Side S/N G2040 and higher

ProX-1630 BIOS settings

Press DEL key to enter setup

Standard CMOS:

Drive C:

Drive D:

None
Drive A:

None
Drive B:

None

Video: EGA\VGA

Halt On: All, but keyboard

BIOS Features Setup:

Virus Warning: Disabled
CPU Internal Cache: Enabled
External Cache: Enabled
CPU L2 Cache ECC Checking: Enabled

Quick Power On Self Test:DisabledBoot Sequence:A, C, SCSISwap Floppy Drive:DisabledBoot Up Floppy Seek:EnabledBoot Up Num Lock Status:OnGate A20 Option:FastTypematic Rate Setting:Disabled

Typematic Rate (Chars\Sec):

Typematic Delay (Msec):

Security Option:

PCI/VGA Palette Snoop:

OS Select for DRAM >64MB:

Report No FDD for Win 95:

No

6

250

Setup

Disabled

Non OS2

Video BIOS Shadow:

C8000-CBFFF Shadow:

Disabled
CC000-CFFFF Shadow:

D0000-D3FFF Shadow:

D4000-D3FFF Shadow:

D8000-DBFFF Shadow:

Disabled
DC000-DFFFF Shadow:

Disabled
DC000-DFFFF Shadow:

Disabled

Chipset Features Setup:

Auto Configuration: Enabled EDO DRAM Sped Selection: 60ns EDO CAS X# MA Wait State: 2 EDO RAS X# Wait State: 2 SDRAM RAS -to- CAS Delay: 3 SDRAM RAS Precharge Time: 3 SDRAM CAS Latency Time: 3

SDRAM Precharge Control:

Disabled
DRAM Data Integrity Mode:

System BIOS Cacheable:

Video BIOS Cacheable:

Disabled
Video Ram Cacheable:

Disabled
Disabled

8 BIT I/O Recovery Time: 1
16 BIT I/O Recovery Time: 1

Memory Hole at 15M-16M:

Passive Release:

Disabled

Delayed Transaction:

AGP Aperture Size (MB):

Disabled

64

Auto Detect DIMM?PCI CLK: Enabled Spread Spectrum: Disabled

Power Management Setup:

Power Management: User Define

PM Control by APM:
Video Off Method:
DPMS
Video Off After:
NA

Doze Mode:DisableStandby Mode:DisableSuspend Mode:DisableHDD Power Down:DisableThrottle Duty Cycle:62.5%PCI/VGA Act-Monitor:Disabled

IRQ 8 Break Suspend: Disabled

IRQ [3-7, 9-15] NMI:

Primary IDE 0:

Disabled

Primary IDE 1:

Disabled

Floppy Disk: Disable Serial Port: Disable

Parallel Port: Disable

PNP/PCI Configuration

PNP OS Installed:
Resources Controlled by:
Manual
Reset Configuration Data:
Disabled

IRQ-3 Assigned to:
IRQ-4 Assigned to:
IRQ-5 Assigned to:
IRQ-7 Assigned to:
IRQ-9 Assigned to:
IRQ-9 Assigned to:
IRQ-9 PCI/ISA PNP
PCI/ISA PNP

IRQ-10 Assigned to: Legacy ISA IRQ-11 Assigned to: Legacy ISA IRQ-12 Assigned to: Legacy ISA IRQ-14 Assigned to: PCI/ISA PNP IRQ-15 Assigned to: Legacy ISA DMA-0 Assigned to: PCI/ISA PNP DMA-1 Assigned to: PCI/ISA PNP DMA-3 Assigned to: PCI/ISA PNP DMA-5 Assigned to: PCI/ISA PNP DMA-6 Assigned to: PCI/ISA PNP DMA-7 Assigned to: PCI/ISA PNP

Used MEM Base Address: N/A

Integrated Peripherals

IDE HDD Block Mode:
IDE Primary Master PIO:
Auto
IDE Primary Slave PIO:
Auto
IDE Primary Master PIO:
Auto
IDE Primary Slave PIO:
Auto
On-Chip Primary PCI IDE:
USB Keyboard Support:
Enabled
Disabled

Onboard FDC Controller: Enabled
Onboard UART 1: 3F8/IRQ 4
Onboard UART 2: 2F8/IRQ 3
Onboard UART 2 Mode: Standard

Onboard Parallel Port: Disabled

Chapter 7: Specifications

The following is a table describing the performance characteristics and specifications of the IMMULITE 2000/2500 Analyzer:

	Specifications		
General Specifications:	Throughput:	Up to 200 tests per hour	
	Time to first result:	35 Minutes (IMMULITE 2000) 15 Minutes (IMMULITE 2500)	
	Tests per sample:	Unlimited	
Luminometer Specifications:	Detection method:	Photomultiplier Tube	
	Spectral response:	350 - 500nm (FWHM)	
	Incubation temperature:	37+/0.1°C	
Computer Specifications:	Supplied RAM:	128 megabyte (IMMULITE 2000) 256 megabyte (IMMULITE 2500)	
	Hard drives (3):	Vary in size from 2 GB (Gigabyte) – 40 GB	
	Monitor:	15" Flat Screen Monitor with Surface Acoustic Wave Touch- Screen	
Electrical Specifications (220 Volts):	Power requirements:	55 ± 5 Hz, 6 Amps	
	Power consumption (IMMULITE 2000 only):	At idle - 250 W (average) During Operation - 1000 W	
	BTU rating (IMMULITE 2000 only):	3413BTU/hr	
	Installation Category (Overvoltage Category):	2	
Environmental Specifications:	Operating environment temperature:	Between 18 and 32°c, less than 80% humidity	
	Temperature Control:	Assays incubated at 37°C	
	Pollution Degree:	2	
Fluidics Specifications:	Water used per test:	7.5 mL (approx. 680 tests per full water reservoir)	
	Probe Wash used per test:	2.0mL (1650 tests per full Probe wash container)	
	Substrate used per test:	0.200mL (1000 tests per full substrate reservoir)	

	Specifications	
Physical Specifications:	Dimensions:	Height: 79" (200cm), with lid up
		Width: 59.7" (151cm)
		Depth: 29.7" (75cm)
	Weight:	890 lb. (403.70 kg)
Decibel Rating	dBm	65 dBm when all motors are running
		52 dBm when in idle mode

EC Declaration of Conformity according to directive 98/79/EC

DPC Cirrus Inc. 62 Flanders-Bartley Road Flanders, NJ 07836 a subsidiary of Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045-5597

declare under sole responsibility that the following equipment to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other

normative documents. If changes declaration of conformity is no lor	s are made to the product which is covered by this declaration of conformity, the nger valid.	
Equipment type:	In Vitro Diagnostic Medical Device	
Model:	IMMULITE® 2000	
Serial Number:		
EC Directives:	93/68/EC, 89/392/EC (91/368/EC, 93/44/EC), 73/23/EC, 89/336/EC	
Harmonized Standards Used:	EN55011, EN60555-2, EN60555-3, EN50082-1, EN61000-3-2, EN61000-3-3	
National and other standards and technical specifications:	IEC 1010-1, IEC 801-2,3,4, IEC 1000-4-2, IEC 1000-4-4, ENV50140, ISO 9001:1994 (BS EN ISO 9001:1994), 21CFR, Part 820 FDA cGMP, EN46001: 1996; ISO 13485: 1996; UL 3101, Laboratory Equipment	
Notified body according to Annex VII:	Not Applicable	
employed to hold the documenta	ation and evaluate the safety issues of this equipment.	
Date/Signature of manufacturer or responsible party:	· 	
Title of signatory:	Vice President, Regulatory Affairs and Quality Systems 2000	
Date/Signature of EU representa or responsible party:	ative	
Title of signatory:		

We,

DPC Cirrus Inc. 62 Flanders-Bartley Road Flanders, NJ 07836 a subsidiary of Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045-5597

declare under sole responsibility that the following equipment to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

declaration of conformity is no fo	niger vand.
Model:	IMMULITE® 2500
Serial Number:	
EC Directives:	93/68/EC, 89/392/EC (91/368/EC, 93/44/EC), 73/23/EC, 89/336/EC
Harmonized Standards	,
Used:	EN55011, EN60555-2, EN60555-3, EN50082-1, EN61000-3-2, EN61000-3-3
National and other	IEC 1010-1, IEC 801-2,3,4, IEC 1000-4-2, IEC 1000-4-4,
standards and technical	ENV50140, 21CFR, Part 820 FDA cGMP;
specifications:	ISO 13485: 1996; UL 3101-1, Laboratory Equipment
Notified body according	
to Annex VII:	Not Applicable
employed to hold the document	ation and evaluate the safety issues of this equipment.
Date/Signature of manufacture or responsible party:	r
Title of signatory: <u>Vice I</u>	President, Regulatory Affairs and Quality Systems 2000
Date/Signature of EU represent or responsible party:	tative
Title of signatory:	

Chapter 8: Preventive Maintenance

8.1 Introduction

This section describes the procedures to perform bi-annual preventive maintenance on the IMMULITE 2000 and IMMULITE 2500 systems.

This procedure reflects the Preventative Maintenance process for both systems. When the procedure differs for the system it will be noted within the text of the document.

8.2 Materials

The materials required to perform preventive maintenance are as follows:

Fluke 75III Multimeter or Equivalent

Adjustable Pipette (10 – 1000 μL) Eppendorf or Equivalent

502707, IMMULITE 2000/2500 Reaction Tubes

13 x 100mm Sample Tubes

12 x 75mm Sample Tubes

8.3 Procedure

If any Motor Positions are changed during the Preventative Maintenance, verify them and make an IML File to transfer the new "Position.iml" file to the Control PC. When performing preventative maintenance on the IMMULITE 2000/2500 Analyzer, follow these steps:

Note: This procedure can be done out of sequence.

General Overview

- 1. Discuss past performance with customer.
- 2. Check Event Log using the password "C1RRUS," enter the Detailed view of the Event Log to look for any unusual or recurring problems with the IMMULITE 2000/2500.
- **3.** Make any necessary upgrades (retrofits). Depending upon the manufacture date of the Instrument, install any needed Retrofits.
- **4.** Change Main Fan Filter.

- **5.** Replace CO₂ scrubber tube.
- **6.** Replace Dilution Well Insert install the new insert provided in the PM Kit (insure that it is pressed down and fully seated in the brass fitting). Verify the Dilution Well Bottom Position is configured properly.
- 7. UPS The UPS sustains power when unplugged. Remove the power plug from the wall and confirm that the "Back Up Battery" toggles on, keeping the IMMULITE 2000/2500 running.

<u>Note:</u> To perform this procedure, ensure that the IMMULTIE 2000 is at the "CTRL-ALT-DEL" screen. For, the IMMULITE 2500, ensure you are at the Windows XP Log On Screen. This prevents damage to the Windows NT and Windows XP Shells as well as the IMMULITE 2000/2500 software.

Power Supply

Note: The voltages MUST be checked at the Driver PCBs.

- 1. Check voltages at DC Distribution PCB Test Points.
- 2. +24 VDC (+23.76 VDC to +24.24 VDC) Test Point 1 and Test Point 2.
- **3.** 24 VAC Check at J12.
- **4.** +12 VDC (+11.88 VDC to +12.12 VDC) Test Point 5 and Test Point 6.
- **5.** -12 VDC (-11.88 VDC to -12.12 VDC) Test Point 7 and Test Point 6.
- **6.** To check the +5 VDC, go to the Sample Carousel Driver PCB, P/N 450104. Measure across Pins 1 and 2 of Connector J2. The voltage at this point should be at least +5 VDC. An acceptable range is +5.00 VDC to +5.20 VDC.
- 7. Check voltages at PMT Power Supply.

<u>Note</u>: Removal of the Gold Protective Casing will be required to measure these voltages.

At Connector J2, J3, or J4, you will be able to measure the \pm VDC. Pin 2 of each connector is the common ground. Pin 3 is the \pm VDC and Pin 1 is the \pm VDC (ranges).

DRD Module

Replace the Upper and Lower Seals by disassembling each Dilutor in the following manner.

<u>Note</u>: It is recommended to wear rubber gloves to avoid contaminating the Dilutor Assembly.

<u>Note</u>: The upper piston housing is of the aluminum style. The lock nut must be loosened first.

- **1.** Move the Dilutor to the Bottom position.
- 2. Loosen the upper piston housing by turning it to the right.
- **3.** Remove the two shoulder screws.
- **4.** Gently remove the black "top hat", P/N 501682, and the clear acrylic piece, P/N 501543.
- **5.** Unscrew the upper piston housing from the black Top Piston Support, remove and discard the spring, and replace it with the enclosed spring.
- **6.** Carefully remove the Upper Seal, P/N 901635, and the Lower Seal, P/N 901634. Replace with new enclosed seals.

<u>Note</u>: Insure that the Seals are installed correctly. Improper installation will cause leaks and poor priming. After installation of these parts, reassemble the Dilutor.

<u>Note</u>: Make sure the upper piston housing is **HAND** Tightened to the left (clockwise).

- **7.** Lubricate the Sample and Reagent DRD. Refer to Kit 422106, DRD Lubrication Kit.
- **8.** Verify Dilutor Positions (remember to HOME the dilutor properly before verification).

<u>Note</u>: If changes are needed, follow the instructions for Configure Sample and Reagent Dilutors below.

Sample and Reagent Dilutor Configuration Procedure

<u>Note</u>: For Verification of Dilutor Positions please refer to Chapter 9 – Repair Information, Section 9.4.

Dual Pipettor Module

<u>Note:</u> Replace Sample and Reagent Probes before proceeding with this section. It is recommended to run the following diagnostics to check the Probe Dispense.

Verify probe Angle dispense by running the following diagnostics:

- Sample Probe Angle run Sample Probe Dispense Angle. It should be < 3.5 degrees.
- Reagent Probe Angle run Reagent Probe Dispense. It should be < 3.5 degrees.

Lubricate Pipettor Lead Screws utilizing a Teflon based lubricant.

<u>Note:</u> Serial numbers E0920 and up DO NOT NEED LUBRICATION. For All IMMULITE 2500 systems **NO** Lubrication is required.

Realignment of Critical Sample Carousel and Sample Arm X & Z Positions

<u>Note</u>: For Verification of Sample and Reagent Positions please refer to Section 9.2.0 for the Sample Pipettor positions and Section 9.2.1 for the Reagent Pipettor.

Verifying Tube Bottom Position

Follow the steps listed below to verify the Sample Arm Z position "Tube Bottom".

- 1. Insert a 12 x 75 mm PLASTIC tube containing 75 μ L of Diluent or Control Sample into Rack A, position 1.
- 2. Move the Sample Carousel to the A1@Pipettor position.
- 3. Move the Sample Arm to the OUTERSAMPLE position in the X-direction. At this point, the Sample Arm should be directly centered above Sample Rack A, position 1.
- 4. Begin moving the Sample Pipettor arm down until the Level Sense LED flickers. Compare the saved Hexadecimal Value to the value present in the encoder position box. The values should be within approximately 6 steps of one another. If this is not the case, repeat steps 7-10, ensuring that 75 μ L of Diluent was pipetted correctly and that the Sample Pipettor arm was properly homed.

<u>Note</u>: If repeating the verification process does not produce satisfactory results, resetting the "Tube Bottom" position may be necessary. Please refer to Section 9.2.0

Bead Pack Carousel

Note: For Verification of Bead Carousel Positions please refer to Section 9.2.5.

Tube Hopper Module

Check the operation of the sensors for the queue, bead, and upper and lower hopper sensors.

- 1. Run the Diagnostic test "Sensor Test".
- **2.** Place Reaction Cup(s) in front of the appropriate sensor to see if it changes state from green to red.
- 3. Verify the Tube Indexer Positions using the following instructions:

Tube Indexer

Please refer to Section 9.2.5 for verification of Tube Indexer Positions

- Check Queue for smooth reaction tube movement. This can be verified by aligning the Tube Indexer at the queue position. Then begin to slide Reaction Cups down the queue to ensure there is a smooth transition from the queue to the tube indexer.
- For IMMULITE 2000 Systems B0001 H2724 to avoid stray bead detect errors it is recommended to shim the Bead Detect Sensor. This can be done by installing a #4 Flat Washer with the mounting screw for the Bead Detect Sensor.

<u>Note</u>: If the system has had the Tube Indexer Module replaced in this serial number range; after shimming, it is imperative to check to make sure Reaction Tubes **DO NOT** jam when moving from the *Queue* to the *Bead Drop* Position. If this occurs removal of the shim will be necessary.

For ALL IMMULITE 2500 systems shimming is not necessary.

- Test Analog Bead Sensor (400635)
- 1. Cover a reaction cup with black electrical tape (as shown in Figure 1 below).
- Go into Diagnostics / Special Testing (Password-IML2000) / Motor Configurations / Slave 2 / Tube Indexer (At the top right of the screen it displays the BEAD OUTPUT)
- 3. Place the covered reaction tube in the Tube Indexer, and move the indexer disk to the Bead Drop position (Via software). Insure the Indexer is properly aligned.
- 4. Observe the Bead Output value. The value must be less than 20.

5. If the Value is greater than 20, the sensor assembly (400635) must be replaced.

The failure mode would be one of the following conditions

- A value greater than 20, but less than 100 would indicate a leakage current on the sensor base. Flux residue between the transistor leads creates a path for current flow. This would increase the probability of false 407 – Extra Bead Detected errors
- A value is greater than 100 would indicate an internal sensor failure. This failure mode would decrease the sensors ability to detect two beads in a single reaction cup.

Verify the value indicating failure is correct by completely blocking the collector side (rear) of the Sensor Assembly (Figure 2). If the value is consistent at greater than 20, the sensor must be replaced.

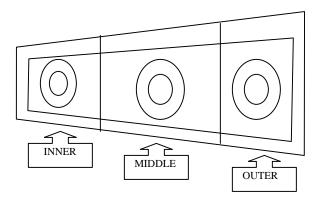




Figure 1 Figure2

Reagent Carousel

Note: For Verification of Reagent Carousel Positions please refer to Section 9.2.4.



The following section will focus first on the components IMMULITE 2000 Tube Processing area and then on the IMMULITE 2500 Tube Processing Area.

<u>Tube Processor Module (IMMULITE 2000)</u>

Note: For Verification of Tube Processor Positions please refer to Section 9.2.6.

- Replace Lubricated Detent Disk Gasket located in the Luminometer section of the Tube Processor.
- Clean the Solid Waste Exit Chute and Tube Drop section of the Tube Processor.
- Install the Waste Manifold Insert, P/N 503301 from Kit 422165.
- Run the diagnostic, "Tube Chute Test." The value in the small green box at the lower right hand corner of the screen that reads, "PORT 402 S0" should change from "00" to "80" when blocked with Reaction Cups.
- Check functionality of Geneva Drive Assembly. Exercise the Geneva Indexer four (4) times to ensure that the transfer baffles have no backward movement at the start of its movement.
- Ensure the Tube Lifter Spring has a compression of approximately 1/8 inch.

To verify the Tube Lifter Spring Compression, complete the following steps:

<u>Important:</u> Once the Tube Lifter Shaft is HOMED, use only the UP and DOWN positions. If you accidentally use the HOME position after it has been HOMED, you *must* redo the HOMING procedure.

- HOME the Tube Lifter.
- Move the Tube Lifter Shaft UP 100 steps.
- HOME the Tube Lifter again. The decimal reading in the encoder position should be approximately –40. The HOME sensor will be RED.
- Left click the UP position. The Tube Lifter Shaft should be just below the Transfer Chain Baffle. It will appear to almost touch the baffle.
- Left click the DOWN position to move the Tube Lifter Shaft down.

- Place a Reaction Cup on the Transfer Chain Baffle.
- Reinstall the Wash Station and create the following program:

Enter "Create Programs"

Go to the Stepper Motors Column

Choose "Tube Lifter => "UP"

Click "RUN TEST." "RUN"

You will hear the Tube Lifter move to the "UP" position and stay there energized. From the rear of the IMMULITE 2000 by the Exit Chute, you can see the Tube Lifter Assembly. While viewing this assembly, confirm that between the Retaining Clip and the Tube Lifter Carriage, P/N 501032, there is approximately 1/8 of an inch (.32 cm) gap.

Incubator (IMMULITE 2500)

Please refer to Section 9.5.2 and Section 9.5.4 for verification of alignments of the following areas of the Incubator Module (Incubator Belts 1 & 2, Incubator Cover)

- o Tension the Incubator Belts by loosening the mounting screws. Once tensioned retighten screws.
- o Verify Alignments of Incubator
- O Verify Tube in Place Sensors Functionality There are currently 7 Tube In Place Sensors on the IMMULITE 2500. On Incubator Belt 1, there is the sensor at the Inlet position. On Incubator Belt 2, there are sensors at the Belt Transfer, Pipette, Wash 1 and Wash 2 positions. On the Luminometer Belt, there are sensors at the Wash 1 and Wash 2 positions.

Sensor Depth

Verify that the corresponding LED on the 450195 PCB in the Electronic Chassis is OFF.

Place a tube in the belt in front of the sensor. Align the sensor to the center of the tube keeping the mounting bracket straight.

Make sure the tube is fully seated in the baffle and verify that the corresponding LED on the 450195 PCB is ON.

Slowly move the tube away until the front of the tube reaches the middle of the baffle. Verify that the LED is still ON.

If the LED is off, move the sensor closer to the tube and repeat the above steps for Sensor Depth until the condition is met.

(Make sure the sensor does not interfere with the belt movement.)

Clockwise and Counter Clockwise Movement

Run the appropriate "Tube in Place" Diagnostic to adjust each sensor.

TIP Inc1 Inlet test
TIP Inc2 Belt Xfer test
TIP Inc2 Pipette test
TIP Inc2 Wash 1 test
TIP Inc2 Wash 2 test
TIP Lum Wash 1 test
TIP Lum Wash 2 test

If adjustment is required a well centered Tube in Place Sensor with at least +/- 5 steps Clockwise and Counter Clockwise is required. If this is unattainable replacement of the Tube in Place sensor may be required.

Luminometer Module (IMMULITE 2500)

(Luminometer Belt, Luminomter Disk, PMT Transfer and Exit Transfer Arm) Please refer to Section 9.5.3 and Section 9.5.4 for verification of alignments of the following areas of the Luminometer Module.

- o Tension the Luminometer Belt by loosening the mounting screws. Once tensioned retighten screws.
- o Verify Alignments of Luminometer
- Verify Tube in Place Sensors Functionality
 Refer to alignment process shown in the Incubator Module section.
- o Replace Solid Waste Exit Chute.

Wash Stations (IMMULITE 2500)

- o Inspect Sump Area to insure no build up material has been occurred. Clean spindle gear of any build up to help ensure proper washing of Reaction Tubes.
- o Please refer to Section 9.5.3 for verification of alignments of the Wash Stations.

Sample Carousel

Note: For Verification of Sample Carousel Positions please refer to Section 9.2.3.

- 1. Replace the Sample Carousel Ground Brush. Once replaced, ensure that the Brass Brush is touching the unfinished portion of the Sample Carousel to allow for proper grounding. The resistance reading should be less than 6 Ohms when measured between one of the screws holding the black sample rack guide blocks and ground.
- 2. Turn the Barcode Reader Laser Scanner on by going to C:\DPC\C\File Transfer.exe and enter "Control Utilities" and select "BarCode Scanner" => "Bar Code Scan Rate." Ensure that the reads have a range from 300 500 decodes per second. This range will include the Sample Rack ID, Inner and

Outer Sample Carousel and Reagent Carousel.

<u>Note</u>: If the customer has printed labels, they should also be checked to ensure they fall within the prescribed range.

Solenoid Pumps/Linear Actuator Pumps

- 3. Check the volume of both the Substrate and Water Pumps. The Substrate Pump should dispense a consistent 200 μ L (+/- 10 μ L). The Water Pump should dispense a consistent 400 μ L (+/- 20 μ L). If either pump dispenses inconsistently, it is recommended that it be replaced.
- **4.** Check the drawback of the Substrate and Water Pumps. In both cases, the air slug should be ½ inch (0.64 cm) plus or minus 1/8 inch (0.32 cm).

Notes:

- If adjustment is required for the Linear Actuator pumps please refer to Appendix F.
- If adjustment of the drawback is required for the Soleniod Pumps, use RP4 for Water and RP3 for Substrate. These potentiometers are located at the TOP of the Digital Fluidics PCB, P/N 450116 on the Fluidics Assembly.

Fluidics

- 1. Replace Water and Probe Wash In-Line Filters (P/N 901205).
- 2. Replace Hydrophophobic Air Filters in Bottles (P/N 900966).
- **3.** Replace corrugated tubing (P/N 901782) along with the Waste Bottle Valve (P/N 90185).
- **4.** Once installed, lubricate the O-Ring using a silicon-based lubricant to ensure a good seal with the Liquid Waste Bottle Cap and proper drainage.
- **5.** <u>IMMULITE 2000 Only:</u> Remove the Wash Station Assembly and clean the entire area including the bottom of the Wash Station, the Spline Gear, and the Reservoir Assembly (P/N 400569).
- **6.** *IMMULITE* **2000** *Only:* Replace the Waste Trap Kit, P/N 422250.

- 7. <u>IMMULITE 2500 Only:</u> Replace the tubing, elbow and reducer between the Gray Drain Tubing and the Vacuum Pump (501583-11, 501583-06, 900957-0, 901661, 900691-08).
- **8.** Replace the Dilution Well Drain Tubing, P/Ns 901691-23 and 901691-27, along with the Elbow P/N 900957-09, between the Dilution Well and the Drain Manifold.
- **9.** Check all tubing between the respective valves and manifolds. Ensure that the fittings are tight and the tubing is free of kinks.
- **10.** Check all tubing within the component deck for discoloration and possible occlusion. Replace as necessary.

Decontaminate the Entire System and Transducer Cavity

- Decontamination Use to decontaminate the Instrument
- Transducer Decon Use to decontaminate the Transducer Cavity
- Refer to Appendix D for decontamination recommendations
- 11. Run the Diagnostic Program "Watertest" to test the water supply. Your OPEN results for the Reaction Tube with Substrate and Water as well as the Reaction Tube with Substrate alone should be greater than 200, but less than 1250 after both being multiplied by the IMMULITE 2000/2500's PMT Factor. The difference between the two results should be less than 200.
- **12.** Check the Transducer Waveform by performing the following:
 - Put a Test Tube with at least 250 μL of Pbs or similar in Position A1. Ensure the Transducer is well primed (you can use the program "Clot Prime) as well as the system (you can use Prime DRD #2).
 - Enter Service Level of Diagnostics.
 - Click on CLOT Analyze (on the right hand side of the screen).
 - Choose "Clot Test #1." Once this program starts, a white screen will display with options on the top and bottom. At the bottom left will be the word "ACQUIRE." From the three color options, select "RED." The Instrument will go through the program and aspirate a sample of the Pbs.
 - There will be a display of memory on screen. If it is all zeros, there is an electrical problem. Close out of the screen by clicking the "x" in the display box.
 - Finish the test by clicking the right side of the screen where the word, "LOAD" is displayed. From the three color options, select "BLUE" and choose, "No Clot." Now compare your sample, the Red Waveform on the Blue Waveform, which is what a perfect "no clot" looks like.
 - If they are similar, the Transducer is okay. If not, make sure the Transducer was well primed. If the Transducer was well primed, run "Transducer Decon." If none of this works, then it is possible that the sample probe or Transducer is faulty.

- **13.** Confirm that the Vacuum Pumps are working and draining properly for the IMMULITE 2500. This is done by utilizing the following program, and dispensing water into the Reservoir Assembly:
 - 1. Create Programs
 - 2. Pick Command: Vacuum Pump "ON"
 - **3.** Pick Command: Wait for Button and type the message, "TURN PUMP OFF"
 - **4.** Pick Command: Vacuum Pump "OFF"
 - 5. "RUN TEST"
 - **6.** "RUN"

This will continually run the Vacuum Pump until the "Wait for Button" is selected.

Computer Software

Verify the Instrument's CAF and PMT Factor, as well as the Software Version in the RUN IMMULITE Software. In Windows NT Explorer, perform the following:

- **1.** <u>IMMULITE 2000 Only:</u> In the TEMP folder in Windows NT Explorer, delete all files except for the current date.
- **2.** Verify the database has been backed up in the last 24 hours.
- **3.** Confirm that "CLOT DETECTION" in C:\DPC\C\File Transfer.exe.
- **4.** Perform Scan Disk on the Control Side Computer utilizing a Monitor and Keyboard.

Use the <Esc> key to exit the control software.

At the C:\BIN, run the DOS command SCANDISK to run the scandisk program.

Select "Yes" to run a thorough scandisk. Running scandisk after ghosting will ensure possible bad sectors of the hard drive will be identified and not used. If the scandisk program indicates several bad sectors or takes an unusually long time, the hard drive should be replaced.

- **5.** Ensure both User and Control CPU Fans are spinning.
- **6.** Verify functionality of Floppy Drive.

Temperatures

Verify that all temperatures are within range. These values should be read at the "View Temperatures" screen in the "RUN IMMULITE" software.

Final Checkout

- 1. Verify the integrity of the IMMULITE 2000/2500 by running available Chemistries at the account. If adjustment of the Assay is required, do this prior to running controls.
- **2.** It is recommended to run 20 replicates of each level of control to ensure precision of the IMMULITE 2000/2500.
- **3.** Attach resulting chemistries to Preventive Maintenance Checklist.

Chapter 9: Repair Information

9.1 Tools and Equipment

To properly service the IMMULITE 2000/2500, certain tools and equipment are required. Some of these tools are not used very often, but are absolutely necessary for specific tasks. For example, the retaining "O" ring pliers are seldom used but, if the need arises to remove or install a retaining ring, no other tool would be a suitable substitute. The list of tools and equipment that a service person should have when servicing an IMMULITE 2000/2500 is as follows:

- Ball-point hex key set (1/20", 1/14", 5/65", 3/32", 7/64", 1/8", 9/64", 5/32", 3/16")
- Hex driver blade set with driver handle (same sizes as above)
- 4-inch and 8-inch blade extension
- Metric ball-point hex key set (1.5mm, 2mm, 2.5mm, 3mm, 4mm, 5mm)
- Large, slotted screwdriver (1/4" tip, 4" blade)
- Small, slotted screwdriver (1/8" tip, 4" blade)
- Large Phillips screwdriver (#2 tip, 4" blade)
- Small Phillips screwdriver (#1 tip, 4" blade)
- o 90° Offset Phillips screwdriver
- Flashlight
- 4" and 6" diagonal pliers
- Wire strippers 26-16 American wire gauge (Awg)
- Retaining ring pliers (reversible)
- Right-angle retaining ring pliers
- o 5-6" Scribe
- o Potentiometer adjustment tool
- Tweezers
- Large (13") and small (5") pickup tools
- o Inspection mirror
- Soldering iron (with solder and a solder-removal device)
- o Miniature slotted screwdriver, 1 mm blade width
- Digital multimeter (capable of measuring 1100vdc)
- Small pieces of fine- and medium-grade sandpaper
- o Miniature open-end wrench set (1/4", 5/16", 3/8")
- Logic probe
- Locate small-screw threadlocker #222

<u>Note</u>: Since some of the tools listed are not readily available outside of the United States, any or all of the above can be purchased from DPC Instrument Systems Division, Inc.

9.2 The Configuration Table

The Motor Position Configuration Table

- o contains all of the mechanical adjustment information for the IMMULITE 2000/2500
- o allows mechanical adjustments to be made via software
- o consists of two synchronized files, one on each the User PC and Control PC in their respective format

When the IMMULITE 2000/2500 is first assembled, it is loaded with a generic configuration table. As each module in the instrument is aligned, the values in the configuration table change to reflect the instrument into which it has been loaded. When all alignments have been completed, the instrument and configuration tables are considered a unit.

The Configuration Table is a database file with the name MOTORFIG.MDB, and is located in the C:\IMMULITE2000\DiagConfig folder of the User PC. When setting mechanical alignment positions using the Motor Configuration program of the Diagnostic Tester, changes are recorded in this database on the User PC. Positions are determined by optical encoder feedback as a hexadecimal value. When alignment is complete, a utility program is used to extract the hexadecimal position values from the MOTORFIG.MDB file to create a new file, named POSITION.IML, in a format recognized by the Control PC. This new file is then automatically transferred to the Control PC C:\Bin directory via the Dual Port Ram.

9.2.2 Configuring Motor Positions and Creating the Position.IML File

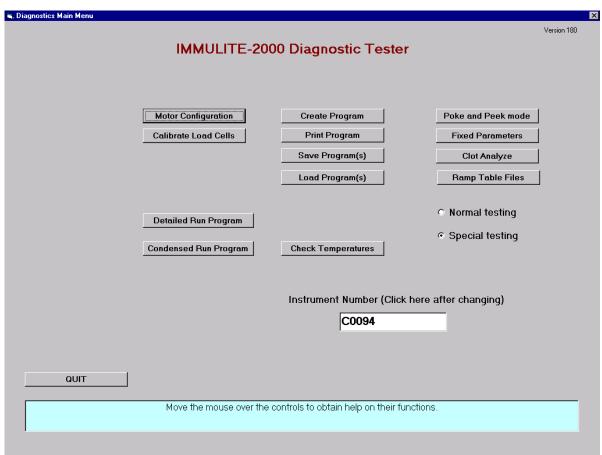
For each of the motors listed, you will be configuring motor positions in the Diagnostic Tester and creating the POSITION.IML file. The POSITION.IML file contains all information necessary for the IMMULITE 2000/2500 to position its components correctly when executing the main operating program. Each position in POSITION.IML file is unique to a particular instrument and is critical to its operation. Therefore,

- If the *control software hard drive* is changed, the POSITION.IML file must be transferred over to the replacement hard drive.
- If any *motor configuration* is changed, the POSITION.IML file must be updated in order for the change to be implemented by the control software.

To configure the motor positions and create the POSITION.IML file, use the following steps:

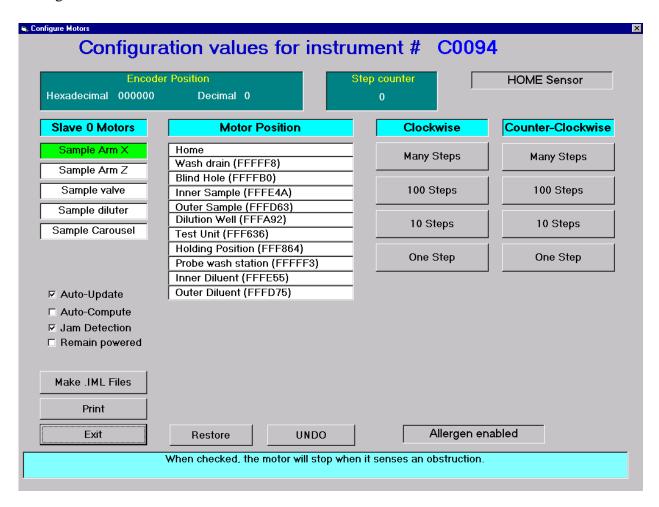
- 1. Open the Diagnostic Tester Program from the Desktop Icon.
- **2.** Select Special Testing mode, and enter the password (1ML2000) when prompted. The **Diagnostics Main Menu** appears.

Figure 14
Diagnostics Main Menu: Motor Configuration Option



3. Select the **Motor Configuration** menu option. The **Configure Motors** screen appears.

Configure Motors Screen



4. Select the Slave and motor to be configured by clicking the left mouse button on their respective buttons. Ensure the **Auto-Update** and **Jam Detection** features are selected when viewing or configuring motor positions.

<u>Note:</u> Always click the Left Mouse Button when selecting a Slave or Motor position. Clicking the Right Mouse Button will alter the saved hexadecimal value permanently.

- **5.** Visually check the position, then move the motor to correct the positioning, by doing one of the following:
 - Click the left mouse button on the motor direction buttons to move the number of steps required.
 - Touch the motor direction buttons on the touch screen monitor.

Note: Prior to viewing or configuring motor positions, the **HOME** position for that motor must be selected to establish the reference position. Once the **HOME** has been established, it is not necessary to redefine **HOME** prior to configuring multiple positions for the same motor. When establishing the **HOME** position for the Sample Arm, Reagent Arm, and Sample Carousel, a multiple step procedure is required to properly define this position. Please refer to the following pages for the proper **HOME** procedure.

6. To save the encoder value identifying the motor position, click the right mouse button on the target name. The encoder value in parentheses, next to the target name, will change to match the hexadecimal encoder value shown at the top left of the screen.

<u>Note</u>: If **Auto-Update** is checked, then the motor can be moved manually to correct its position before saving.

7. When you have configured all motors *OR* when you have changed motor positions, press the button labeled **Make .Iml Files** while in the **Configure Motors** screen to save these positions in the control software. The new **Position.IML** file will be automatically transferred to the Control PC hard disk.

The remainder of this section contains specific descriptions about configuring each motor position. The motor configuration is written in order of appearance in the **Configure Motors** diagnostic screen. In practice, you can configure the motors in any order that combines different components simultaneously for the most efficient setup.

<u>Note</u>: With diagnostic version 210A, auto compute was defaulted to automatically configure each position relative to position 1 of the sample, reagent, or bead carousel.

9.2.3 Configure Slave 0 Modules

HOME Procedure for Sample Arm X & Z Position

Prior to configuring or checking any positions of the Sample Arm, you **must** perform the following seven steps.

- **1. Home** the Sample Arm in the Z-direction.
- **2. Home** the Sample Arm in the X-direction.
- **3.** Move the Sample Arm in the X-direction counter-clockwise 200 steps.
- **4. Home** the Sample Arm in the X-direction.
- 5. Move the Sample Arm in the Z-direction 300 steps down.
- **6. Home** the Sample Arm in the Z-direction.
- 7. Move the Sample Arm to the Z position **Top**

When moving the Sample Arm Z upwards, always move to the position "**Top**." **DO NOT** select the Z position "**Home**" after completing the above steps. If at any time during the configuration process, you select the Z position "**Home**," you **must** repeat the previous seven steps before continuing.

Sample Arm X

Note: Refer to Chapter 4 for micro sampling configurations.

- *Home*—Although this position is not configurable, it is a reference point for all configurable positions. Follow the above procedure for properly defining this reference position.
- Wash drain—Position the probe clockwise from the Blind Hole about half the distance between the outside diameter of the Blind Hole wall and the inside diameter of the Wash Station wall.
- Blind hole—- This shallow wash station well does not have a hole in the bottom. Center the probe in this location
- *Inner Sample* Align the pipettor in a position which will be the center of a 12 x 75 tube in the inner sample rack row.
- Outer Sample- Align the pipettor in a position which will be the center of a 12 x 75 tube in the outer sample rack row.
- *Dilution Well* Make sure the dilution well insert is placed firmly in the dilution well. Center the sample pipettor in the dilution well insert.
- *Test unit* Align the sample pipettor to access a reaction tube in the pipetting position in the tube processor. The probe should be centered over the bead in the reaction tube.
- *Holding position* Align the pipettor over the processor shuttle housing between the dilution well and reaction tube pipetting position. Make sure the probe is not placed over the baffle on the Tube Transport Chain.
- Wash Station- This position is not currently used.
- Inner Diluent- Align the pipettor in a position which will be the center of a diluent tube in the inner sample rack row. Make sure a screw top diluent tube is used to configure this position.
- Outer Diluent- Align the pipettor in a position which will be the center of a diluent tube in the outer sample rack row. Make sure a screw top diluent tube is used to configure this position.

Sample Arm Z

Use the following list to configure the motor positions for Sample Arm Z.

- *Home*—Although this position is not configurable, it is a reference point for all configurable positions. Follow the above procedure for properly defining this reference position.
- **o** *Level sensor* This position is not configurable. When this position is selected, the probe will move down and stop when it has traveled a maximum number of steps (from the database) or when the probe level senses on fluid.
- Wash Drain- Position the probe halfway down (approximately 1700 steps from "TOP") into the center drain in probe wash station.
- Blind Hole Position the probe so that it stops 25 steps above the bottom of the blind hole station.
- Test Unit- Position the probe so that it stops 10-15 steps above the bead in the reaction tube.

- *Holding Position* Go to the Sample arm X Holding location and position the probe 3/8" above the processor shuttle housing.
- o *Inside Wash* Position the probe above the blind hole but below the top edge of the wash station. The probe should be high enough so that it can move from the Wash Drain X-position to the Blind Hole X-position without obstruction.
- *Top* This is the highest point without jamming when at the *Test unit* position (the most counterclockwise position). This position is approximately 100 steps down from the mechanical stop.
- 0.2 mL in Dil Well-Dispense a total volume of 0.2 mL into the dilution well insert and click on LEVEL SENSE. The probe will move down until it level senses on the liquid.
- 0.5 mL in Dil Well- Dispense a total volume of 0.5 mL into the dilution well insert and click on LEVEL SENSE. The probe will move down until it level senses on the liquid.
- 1 mL in Dil Well- Dispense a total volume of 1.0 mL into the dilution well insert and click LEVEL SENSE. The probe will move down until it level senses on the liquid.
- o *Dilution well Bottom* Move the probe down until the TIP JAM flag begins to move upwards. Single step in the UP direction until the TIP JAM flag returns to its normal position. Move up 20 steps and set the position.

Configure the dilution well bottom with the following steps:

- 1. Enter the Diagnostics Tester, Special Testing Mode, Motor Configuration and Slave 0.
- 2. Remove the Sample Probe. Install the Fixture Probe Housing Level Sense (200462).
- 3. Remove the Dilution Well Cover and Insert.
- 4. Home Sample Arm Z. Home Sample Arm X. Move Sample Arm-X 200 steps CCW. Home Sample Arm-X. Move Sample Arm-Z 200 steps DOWN. Home Sample Arm Z. Click on TOP. (DO NOT use HOME to move the sample arm up after performing the above steps; use the TOP position instead of HOME).
- 5. Place the Fixture Sample Tube Configuration on top of the Dilution Well Shaft. (Lettering facing up (200463)).
- 6. Move the Sample Arm-X to the "Dilution Well position".
- 7. Level sense on to the Fixture Sample Tube Configuration (200463).
- 8. Move up Sample Arm-Z 10 steps.
- 9. Remove the Fixture Sample Tube Configuration (200463).
- 10. Move Sample Arm-Z down 824 steps. Right-click this position as "Dilution Well Bottom". Save configuration by clicking the "Make. IML Files" button.
- 11. Re-install the Dilution Cover and Insert.
- Wash Station This position is not currently used.
- Above PW Station This position is not currently used.
- Tube Bottom- Configure the Sample Carousel Tube Bottom.
 - 1. Enter the Diagnostics Tester, Special Testing Mode, Motor Configurations and Slave 0.
 - 2. Remove Sample Probe. Install the Fixture Probe Housing Level Sense (200462). Home Sample Arm-Z. Home Sample Arm-X. Move Sample Arm-X 200 steps CCW. Home Sample Arm-X. Move Sample Arm-Z 200 steps DOWN. Home Sample Arm-Z. Click on TOP. (DO NOT use HOME to move the sample arm up after performing above steps; use the TOP position instead of Home.) Move Sample Arm-X to the "Outer Sample" position.
 - 3. Remove Rack "A" from the Sample Carousel. Home Sample Carousel. Move Sample Carousel 300 steps CCW. Home Sample Carousel.
 - 4. Move Sample Carousel to position the "A1@ Pipettor " position.
 - 5. Place the Fixture Sample Tube Configuration (200463) on the Sample Carousel below the probe

- housing. (Lettering facing up).
- 6. Level sense on to the Fixture Sample Tube Configuration (200463).
- 7. Move Sample Arm-Z 10 steps up. Remove the Fixture Sample Tube Configuration (200463). Move Sample Arm Probe-Z 100 steps down.
- 8. Right-click this position as a temporary "Tube Bottom".
- 9. Move the Sample Arm-Z to the "TOP" position.
- 10. Place the Fixture Sample Tube Configuration (200463) back on the Sample Carousel below the Probe Housing. Level sense on to the Fixture Sample Tube Configuration (200463). Note the decimal value of the encoder in the upper left corner of the screen.
- 11. Move the Sample Arm Z to the "TOP" position.
- 12. Level sense five times, making note of the decimal value of the encoder each time. Note that the encoder position of the fifth level sense is within three steps of the previous level sense.
- 13. Right-click on the "TUBE BOTTOM" position. Save configuration by clicking on the "Make. IML Files" button.
- 14. Re-install the Sample Probe.

<u>Note</u>: It may be necessary to preset the *Tube Bottom* position to the point where the Tip Jam Sensor triggers at the bottom of a sample tube, prior to identifying the actual *Tube Bottom* position, if the current position is higher than the new set point.

Sample Valve

Refer to page 9-30 for instructions for a ceramic style Sample Valve.

- *Home* This position is not configurable. You must **HOME** the motor prior to setting any of the positions.
- Pipette Tip- Position the outlet of the common port in the top left position of the valve.
- Probe Wash- Position the outlet of the common port in the bottom left position of the valve.
- Water- Position the outlet of the common port at the bottom right position of the valve.

<u>Note #2</u>: Make sure that all of the ports are configured to be within a 180° rotation. The valve should not travel more than 180° to reach any one port. This can be accomplished by beginning with the *Water* position, then aligning the ports in a clockwise sequence.

Sample Diluter

Refer to page 9-31 to configure the Sample Dilutor. This diluter is located on the left, closest to the

- *Home*—This position is not configurable. You must **HOME** the motor prior to setting any of the positions.
- *Top*—The separation point between the upper and lower cylinders is centered in the DRD barrel inlet port.
- Middle—This is the separation point between the upper and lower cylinders.
- **o** *Bottom*—This is the farthest extension of the large cylinder without hitting the framework. This position is approximately 100 step up from the mechanical stop.

Sample Carousel

Prior to configuring the Sample Carousel positions, Home the Sample Carousel by following the steps below.

Home Procedure for the Sample Carousel

- 1. Select the Sample Carousel position Home.
- 2. Rotate the Sample Carousel 300 steps counter-clockwise.
- 3. Select the Sample Carousel position Home once again.

Use the following list to configure the motor positions for the Sample Carousel. The positions are listed under the title heading **FIXED SAMPLE POSITIONS**:

- *Home*-This position is not configurable. You must **HOME** the motor prior to setting any of the positions. The procedure above must be followed to properly define the Sample Carousel **HOME** position.
- Reagent View Port-Align sample carousel Opening with reagent carousel window.
- Rack Access-Align sample carousel Rack A with sample carousel access door. The rack should easily engage with the sample carousel when pushed through the rack guide.
- Outer Sensor-Align sample carousel rack position A1 so the tube will illuminate the sensors located on the outside of the sample carousel.
- *Inner Sensor*-Align sample carousel rack position A2 so the tube will illuminate the sensors on the inside of the sample carousel rack.
- A1@pipettor-Align sample rack A1 at the pipettor for Sample Arm X access to a 12 x 75 tube in the outer row. The probe should be centered in the tube.
- A2@pipettor-Align sample rack A2 at the pipettor for Sample Arm X access to a 12 x 75 tube in the inner row. The probe should be centered in the tube.
- A1@pipettor (Diluent)-Align sample rack position A1 at the pipettor for Sample Arm X access to a diluent tube in the outer row. Be sure to use a screw top diluent tube when configuring this position.
- A2@pipettor (Diluent)-Align sample rack position A2 at the pipettor for Sample Arm X access to a diluent tube in the inner row. Be sure to use a screw top diluent tube when configuring this position.

<u>Note</u>: When setting the Inner and Outer Sensor positions, make sure the sensors are close enough to the tubes that both the high and low sensors will see the tube, but, they are far enough back that they will not interfere with a test tube with a cap in place when the carousel is rotated.

• A1 @ Barcode Reader - Position Rack A, Tube 1 so the red line from the laser barcode reader is in the exact center of the barcode on the tube.

<u>Note</u>: These positions are set relative to the laser barcode reader. This Reader can be turned on or off by running the FILETRANSFER.EXE utility from the C:\DPC\C folder. Under the menu heading CONTROL UTILITIES is an option for the barcode reader. Click on the appropriate command to turn the barcode reader on or off as desired. Remember that you must redefine the Sample Carousel **HOME** position when returning to the Motor Configuration mode of the Diagnostic tester.

• Rack A - Position Rack A, Tube 1 so the red line from the laser barcode reader is in the exact center of the barcode on the tube.

Note: The following positions are Auto-Computed once "A1 @ Barcode Reader" has been set.

- Rack A Position Rack A, Tube 1 so the red line from the laser barcode reader is in the exact center of the barcode on the tube.
 - Repeat this alignment for positions *Rack B* through *Rack F* centering a tube in position 1 of each rack at the laser barcode reader.
- Tube 1 Position Rack A, Tube 1 so the red line from the laser barcode reader is in the exact center of the barcode on the tube.
 - Click the blue bar titled **RACKS** (**TUBE 1**) to reach this menu. Use a sample tube when verifying each position.

9.2.4 Configure Slave 1 Modules

Home Procedure for Sample Arm X & Z Position

Prior to configuring or checking any positions of the Reagent Arm, you **must** perform the following seven steps.

- **1. Home** the Reagent Arm in the Z-direction.
- **2. Home** the Reagent Arm in the X-direction.
- 3. Move the Reagent Arm in the X-direction counter-clockwise 200 steps.
- **4. Home** the Reagent Arm in the X-direction.
- 5. Move the Reagent Arm in the Z-direction 300 steps down
- **6. Home** the Reagent Arm in the Z-direction.
- 7. Move the Reagent Arm to the Z position **Top**.

When moving the Reagent Arm Z upwards, always move to the position "**Top**." **DO NOT** select the Z position "**Home**" after completing the above steps. If at any time during the configuration process, you select the Z position "**Home**," you **must** repeat the above seven steps before continuing.

Reagent Arm Z

Use the following list to configure the motor positions for the Reagent Arm Z.

- *Home*—Although this position is not configurable, it is a reference point for all configurable positions. Follow the above procedure for properly defining this reference position.
- Liquid Level Sense- This is not a configurable position. When this position is selected, the probe will
 move down and stop when it has traveled a maximum number of steps (from the database) or when
 the probe level senses on fluid.
- Wash drain- Position the probe halfway down (approximately 1700 steps from "TOP") into the center drain in probe wash station.
- Blind Hole- Position the probe so that it stops 25 steps above the bottom of the Blind Hole.

- Test unit Position the probe so that it stops 10–15 steps above the bead in the reaction tube.
- *Holding position* Go to the Reagent X Holding location and position the probe so that it is as low as possible, but does not interfere with the incubator cover.
- o *Inside wash* Position the probe above the blind hole but below the top edge of the wash station. The probe should be high enough so that it can move from the Wash Drain X-position to the Blind Hole X-position without obstruction.
- *Top* This is the highest point without jamming when at the *Inner reagent* position (the most counterclockwise position). This position is approximately 100 steps down from the mechanical stop.
- *Probe Wash* This position is not currently used.
- Above the PW Station- This position is not currently used.
- Reagent Bottom- This is how to configure the reagent bottom.
 - 1. Enter the Diagnostics Tester, Special Testing Mode, Motor Configuration and Slave 1.
 - 2. Remove the Reagent Probe. Home Reagent Arm-Z. Home Reagent Arm-X. Move Reagent Arm-X 200 steps CCW. Home Reagent Arm-X. Move Reagent Arm-Z 200 steps DOWN. Home Reagent Arm-Z. Click on TOP. (DO NOT use HOME to move the reagent arm up to after performing above steps; use the TOP position instead of HOME).
 - 3. Move Reagent Arm-X to the "Outer Reagent" position.
 - 4. Move Reagent Arm-Z down until it barely touches the mechanical stop. Right click on the "Reagent Bottom" position to temporarily save this position.
 - 5. Move Reagent Arm-Z to the "TOP" position.
 - 6. Install the Fixture Probe Housing Level Sense (200462).
 - 7. Home Reagent Carousel. Move Reagent Carousel 300 steps CCW. Home Reagent Carousel.
 - 8. Place the Fixture Reagent Bottom Configuration in position 1 of Reagent Carousel (200479) with chamfered edge facing down toward the inner carousel tray.
 - 9. Move Reagent Carousel to the "Outer Reagent" position.
 - 10. Level Sense on to the Fixture Reagent Bottom Configuration (200479).
 - **Note**: Be sure the probe is actually level sensing on the fixture.
 - 11. Right-click to save this position as "Reagent Bottom". Save configuration by clicking the "Make. IML Files" button.
 - 12. Re-install Reagent Probe.

Reagent Arm X

Use the following list to configure the motor positions for the Reagent Arm X.

Note: Please refer to Chapter 4 for allergy wedge configurations.

• *Home*—Although this position is not configurable, it is a reference point for all configurable positions. Follow the above procedure for properly defining this reference position.

- Outer Reagent- Move the reagent arm to be centered in the opening of the outer A compartment of a reagent PAK. Move the reagent arm down to check that the probe is centered in the reagent PAK opening.
- *Middle Reagent_* Move the reagent arm to be centered in the opening of the middle B compartment of a reagent PAK. The reagent carousel tray will have to be moved slightly to enable the pipettor access.
- o *Inner Reagent* Move the reagent arm and reagent carousel so that the reagent probe will be centered in the opening for the inner C reagent compartment of the reagent PAK. The reagent carousel tray will have to be moved slightly to enable the pipettor access.
- Wash Drain- Position the probe clockwise from the Blind Hole about half the distance between the outside diameter of the Blind Hole wall and the inside diameter of the Wash Station wall.
- Blind Hole Center the reagent probe in this shallow wash station well which <u>does not</u> have the hole in the bottom.
- *Test Unit-* Align the reagent probe to be centered in the reaction tube in the pipetting position. The probe should be centered over the bead.
- *Holding Position* Move the reagent pipettor to a position close to the pipetting position, with out hitting the incubator cover or the sample pipettor if it is dispensing into the reaction tube.
- *Probe Wash Station* This position is not currently used.

Reagent Valve

Use the following list to configure the motor positions for the Reagent Valve. Refer to page 9-30 for instructions for a ceramic style Reagent Valve.

- *Home* This position is not configurable. You must **HOME** the motor prior to setting any of the positions.
- Pipette Tip- Position the outlet of the common port in the top left position of the valve.
- Probe Wash- Position the outlet of the common port in the bottom left position of the valve.
- Water- Position the outlet of the common port at the bottom right position of the valve.

<u>Note</u>: Make sure that all of the ports are configured to be within a 180° rotation. The valve should not travel more than 180° to reach any one port. This can be accomplished by beginning with the *Water* position, then aligning the ports in a clockwise sequence.

Reagent Diluter

Refer to page 9-31 to configure the Reagent Dilutor. This diluter is located on the right, closest to the Substrate reservoir.

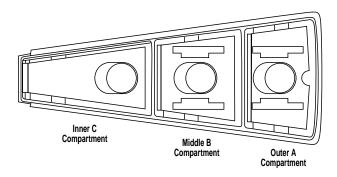
- *Home*—This position is not configurable. You must **HOME** the motor prior to setting any of the positions.
- *Top*—The separation point between the upper and lower cylinders is centered in the DRD barrel inlet port.
- *Middle*—This is the separation point between the upper and lower cylinders.

• Bottom—This is the farthest extension of the large cylinder without hitting the framework. This position is approximately 100 step up from the mechanical stop.

Reagent Carousel

Use the following list to configure the motor positions for the Reagent Carousel. A reagent PAK is required to configure the following positions. (See Figure 17 for an illustration of a Reagent PAK.)

Figure 16
Top View of Reagent PAK



• *Home*—This position is not configurable. You must **HOME** the motor prior to setting any of the positions.

<u>Note</u>: The following positions should be configured with the Reagent carousel cover removed. By first establishing the Reagent Arm X position to the cover access hole, align the PAK in carousel position 1 to the established probe position.

- o 1A outer—Align the Reagent PAK, in carousel position #1, so that its outer compartment (A) is accessible by the reagent probe when the PAK lid is open.
- 1B center—Align the Reagent PAK, in carousel position #1, so that its middle compartment (B) is accessible by the reagent probe when the PAK lid is open.
- 1C inner—Align the Reagent PAK, in carousel position #1, so that its inner compartment (C) is accessible by the reagent probe when the PAK lid is open.
- Reagent 1@loader—Move the reagent carousel to align the Reagent PAK in position #1 to be accessible from the small Reagent Carousel door.

<u>Note</u>: These positions are set relative to the laser barcode reader. This Reader can be turned on or off by running the FILETRANSFER.EXE utility from the C:\DPC\C folder. Under the menu heading CONTROL UTILITIES is an option for the barcode reader. Click on the appropriate command to turn the barcode reader on or off as desired. Remember that you must redefine the Regent Carousel **HOME** position when returning to the Motor Configuration mode of the Diagnostic tester.

• PAK 1@Barcoder- Place a Reagent PAK into Position 1. Align the red line from the Laser Barcode Reader on the line down the center of the PAK.

Note: The following positions are auto-computed once Pak1@Barcoder is confirgured

The following positions are found under the title heading **PAKS 1-12** @**READER**. This title is reached by clicking on the blue bar titled **FIXED POSITIONS**.

• *PAK 1-* Place a Reagent PAK into Position 1. Verify the red line from the laser barcode reader on the center of the PAK.

Repeat this verification for positions *PAK 2* through *PAK 12* centering a PAK in each position at the laser barcode reader.

The following positions are verified under the title heading **PAKS 13-24** @**READER**. This heading is reached by clicking on the blue bar titled **PAKS 1-12** @**READER**.

• PAK 13- Place the Configuration Reagent PAK into Position 13. Verify the red line from the laser barcode reader on the center of the PAK.

Repeat this verification for positions *PAK 14* through *PAK 24* centering a PAK in each position at the laser barcode reader.

Reagent Wedge Lid Opener

Use the following list to configure the motor positions for the Reagent Wedge Lid Opener.

- Close Not configurable. This command in Diagnostics retracts the motor until the sensor closest to the motor is unblocked by the flag.
- Open Not configurable. This command in Diagnostics moves the motor until the flag blocks the sensor opposite the motor.
- Steps-to-Sensor Decimal number. To set this position, select *CLOSE* to retract the motor. Use the motor movement buttons on the screen to position the flag so that the sensor opposite the motor toggles from gray to red. This is seen as ALTERNATE SENSOR in the upper right hand corner of the screen. Once this occurs, extend another 10 steps, right-click to save this position. The STEP COUNTER window will reset to "0," while leaving the Pak Lid Opener in the extended position.

Note: DO NOT let this motor reach a mechanical stop during the configuration. We are setting the actual number of steps in these places because there is no encoder on this motor.

• Steps to Open Lid -

Perform the following steps to open lid:

- 1. Use the motor movement buttons to extend the actuator so that it will reliably open the reagent PAK lid.
- 2. Right mouse click Steps to Open Lid position and the number from the STEP COUNTER window will transfer into the parenthesis next to this motor position.
- 3. Click on *CLOSED* to retract the motor.

To test the Reagent Pack lid, "OPEN" position as it will be used by the main operating software:

• Add together the number of steps recorded for the Steps to sensor position and the Steps to open lid position. Use the Step buttons to move the pack lid actuator out for the total number of steps calculated.

9.2.5 Configure Slave 2 Modules

Use the following information to configure Slave 2 modules.

Bead Carousel

Use the following list to configure the Bead Carousel module.

- *Home*—This position is not configurable. You must **HOME** the motor prior to setting any of the positions.
- PAK 1@dispense—Align the bead carousel bead drop hole in carousel position #1 with the bead drop chute.
- PAK 1@loader—Position the bead carousel so that position #1 is centered in the bead carousel door opening.
- Pak 1@barcode—With a Bead PAK in carousel position #1, align the barcode reader (Welch Allyn SCANTEAM® 3700 CCD) parting line with the Bead PAK molded parting line.

The following positions are found under the title heading **PAKS 1-12 @READER**. This title is reached by clicking on the blue bar titled **FIXED PAK 1**.

• *Pak 1*—With a Bead PAK in carousel position 1, align the barcode reader (Welch Allyn SCANTEAM® 3700 CCD) parting line with the Bead PAK molded parting line.

Note: The following positions are auto-computed once *Pak 1* is configured.

Repeat this verification for positions *PAK 2* through *PAK 12* aligning a PAK in each position at the barcode reader (Welch Allyn SCANTEAM® 3700 CCD) parting line with the Bead PAK molded parting line.

The following positions are verified under the title heading PAKS 13-24 @READER. This heading is reached by clicking on the blue bar titled PAKS 1-12 @READER.

• *PAK 13*- With a Bead PAK in carousel position 13, align the barcode reader (Welch Allyn SCANTEAM® 3700 CCD) parting line with the Bead PAK molded parting line.

Repeat this verification for positions *PAK 14* through *PAK 24* centering a PAK in each position at the barcode reader (Welch Allyn SCANTEAM® 3700 CCD) parting line with the Bead PAK molded parting line.

Tube Indexer

Use the following list to configure the Tube Indexer module.

- Home- Not a configurable position. You must HOME the motor prior to setting any of the positions.
- Queue- Align the tube indexer slot with the tube chute. Slide a reaction tube down the chute to make sure the slot is aligned properly.
- **o** *Bead Drop* Align the tube indexer slot with the bead drop chute. Use the white line on the Tube Indexer disk and the white line on the Motor Mounting Plate for the alignment.
- Tube Transport- Align the tube indexer slot with the tube transport pickup position.

Tube Transporter

Use the following list to configure the Tube Transporter module.

- Home- Not a configurable position. You must HOME the motor prior to setting any of the positions.
- Queue—Align the tube transport clip with the entrance to the pipetting position in the tube processor.

Processor Shuttle

Use the following list to configure the Processor Shuttle module.

- Home- Not a configurable position. You must HOME the motor prior to setting any of the positions.
- Forward—Advance the processor shuttle so as to push the reaction tube completely into the pipetting station without crushing it.
- Backward—Move the processor shuttle back as far as possible without having the stop hit the motor bracket.

Photomultiplier Tube (PMT) Shutter

Use the following list to configure the Photomultiplier Tube (PMT) Shutter module.

- Home- Not a configurable position. You must HOME the motor prior to setting any of the positions.
- Up—Align the top of the trigger probe mount with the top of the trigger probe housing.
- *Down*—Move the PMT shutter down until the trigger probe mount stops moving, then move another 20 steps.

<u>Note</u>: Gentle pressure may need to be applied to hold the Shutter in the *Down* position when saving, due to the spring load of this mechanism.

Bead Dispenser

Use the following list to configure the Bead Dispenser module.

- *No dispense*—This position is not configurable. This command in diagnostics retracts the motor until the sensor closest to the motor is unblocked by the flag.
- *Dispense*—This position is not configurable. This command in diagnostics moves the motor until the flag blocks the sensor opposite the motor.

• Steps to sensor- To set this position, select NO DISPENSE to retract the motor. Use the motor movement buttons on the screen to position the flag so that the sensor opposite the motor toggles from gray to red. This is seen as ALTERNATE SENSOR in the upper right hand corner of the screen, extend 10 more steps. Right Click and save this as "Steps to Sensor". The STEP COUNTER window will reset to "0," while leaving the Pak Lid Opener in the extended position.

<u>Note</u>: <u>Do not</u> let this motor reach a mechanical stop during configuration. We are setting the actual number of steps in these places because <u>there is no encoder</u> on this motor.

o *Steps to push bead* - Use the motor movement buttons to extend the actuator so it will reliably dispense a bead. Right mouse click the *STEPS TO PUSH BEAD* position and the numbers from the STEP COUNTER window will transfer into the parenthesis next to this motor position.

Click on NO BEAD DISPENSE to retract the motor.

To test the Bead Dispense position as it will be used by the main operating software: Add together the number of steps recorded for the *Steps to sensor* position and the *Steps to push bead* position. Use the step buttons to move the bead dispenser out the total number of steps calculated.

9.2.6 Configure Slave 3 Modules

Use the following information to configure Slave 3 modules.

<u>Note</u>: You must remove the incubator, transfer and luminometer covers before configuring the various motor positions on this slave.

<u>Note:</u> Several Alignments of the Tube Processor Area require the use of the Processor Alignment Tool Kit, P/N 422166

Luminometer Chain

Use the following list to configure the Luminometer Chain module.

• Home- Not a configurable position. You must HOME the motor prior to setting any of the positions.

<u>Note</u>: The HOME position for this motor does not correspond to a mechanical flag. We are using the INDEX pulse on the encoder as the sensor. This means that the HOME position of this motor will vary from instrument to instrument.

• Offset- Move the luminometer chain towards the tube exit (step forward) so that a baffle lines up with the transfer in the tube wash station.

<u>Note</u>: If the Luminometer Chain is adjusted to align at the baffle, it is strongly recommended to ensure that the Luminometer Chain Baffle is squarely aligned at the PMT position. A reaction tube must be aligned directly in front of the PMT to ensure a proper read from the PMT.

Luminometer Shuttle

Use the following list to configure the Luminometer Shuttle module.

• *Home-* Not a configurable position. You must HOME the motor prior to setting any of the positions.

<u>Note</u>: The HOME position for this motor does not correspond to a mechanical flag. We are using the INDEX pulse on the encoder as the sensor. This means that the HOME position of this motor will vary from instrument to instrument.

- Back- Move the luminometer shuttle back so as to permit reaction tubes to travel past without interference.
- Forward- Move the luminometer shuttle so that the forward-most position will completely transfer a reaction tube from the wash station into the luminometer chain. If the transfer is inadequate, then a mechanical adjustment to the luminometer shuttle is required. The luminometer shuttle is slotted which allows for this mechanical adjustment.

<u>Note</u>: The Luminometer Shuttle should not travel more than 180° to go from the BACK position to the FORWARD position.

Configuring the Luminometer Shuttle

The Luminometer Shuttle configurations are **extremely important**. Incorrect settings can cause the Shuttle Pusher Bar to contact the tube with a velocity high enough to result in an elastic impact between the reaction tube and pusher bar. This impact causes the reaction tube to jump/tilt resulting in Luminometer Shuttle Jams. Improper configuration of the Luminometer Shuttle can also result in tubes being pushed too far into the Luminometer Chain or the Shuttle Bar can interfere with tubes on the Transfer Chain. A Luminometer Shuttle Alignment Fixture (200508) has been developed to aid in the setup of the Luminometer Shuttle.

- 1. Remove the Spinner Assembly and the Transfer Chain Cover to expose the entire Shuttle area.
- 2. In the Diagnostic Tester, Motor Configuration mode, Slave 3, select Lum. Shuttle and HOME the Lum Shuttle. The shuttle mechanism will cycle and find the HOME position. The HOME position is taken from the index pulse on the encoder and is instrument specific.
- **3.** The Scotch Yoke mechanism that actuates the Luminometer Shuttle has to be placed in its full forward position. This can be done in the following manner:
 - a) Configure the Forward Motor Position by using the Forward 10 steps or One step Command Buttons.
 - b) Move the pusher bar as far forward as possible.
 - c) It is important to set the FORWARD motor position at the most forward point (towards the Lum Chain). At this time, do not worry about the mechanical position of the pusher bar, as it will be adjusted later.
 - d) If at first, the shuttle moves away from the lum chain, continue to use the Forward Command Buttons; do not use the Backwards Command Buttons. The shuttle will eventually start moving forward after it reaches the furthest point backwards and then the furthest FORWARD position can be reached.
 - e) Save this position as the FORWARD.



- **4.** With the Luminometer Shuttle carriage in the full FORWARD position, loosen the two screws that secure the Luminometer Shuttle Pusher Bar and slide it toward the front of the instrument.
- 5. Install the Luminometer Shuttle alignment fixture (200508) into the Luminometer Chain with the pusher bar alignment slot set to receive the Luminometer Shuttle Pusher Bar. (SEE FIGURE 18)
- 6. While pushing the fixture toward the rear of the instrument, slide the Luminometer Pusher Bar into the alignment slot until it is fully seated and tighten the two screws that secure it. The forward mechanical position of the Luminometer Shuttle Pusher Bar is now set. If the pusher installed on the instrument is the old revision with the sensor installed on the Pusher Bar, the Pusher should be completely removed and reinstalled with the sensor placed in the pocket in the alignment slot. There is a possibility that the ears of the sensor will have to be trimmed slightly for the sensor to fit in the slot.
- 7. Remove the Alignment Fixture and Home the Luminometer Shuttle once again.
- **8.** To ensure the position is correct place a reaction tube in the luminometer chain transfer point and move the shuttle to the FORWARD position. Visually check the forward position of the Luminometer Shuttle Pusher Bar by looking at the space between the shuttle and the cup; it must be .060 +/- .010.
- **9.** To set the BACK Luminometer Shuttle position, move the Pusher Bar back until it is back beyond the Transfer Chain Baffle by using the Backwards command buttons.
- **10.** Re-install the Luminometer Shuttle Alignment Fixture (200508) so the BACK position stop block is in front of the Pusher Bar. (**SEE FIGURE 19**)
- 11. While pulling the Alignment Fixture towards the front of the instrument, use the FORWARD command buttons to advance the Pusher Bar forward until it makes contact with the BACK position stop block on the Alignment Fixture. Save this position as the BACK motor position. The BACK position can then be verified by placing a tube in the transfer chain and checking that it takes ~30 steps forward for the Pusher Bar to contact the tube.
- **12.** Check configurations by moving from the BACK position to the FORWARD position and then to the BACK position. When the shuttle is configured correctly, it should move in only one direction during the entire movement from BACK to FORWARD or FORWARD to BACK.
- **13.** Make an IML File.

Figure 18 Forward Position

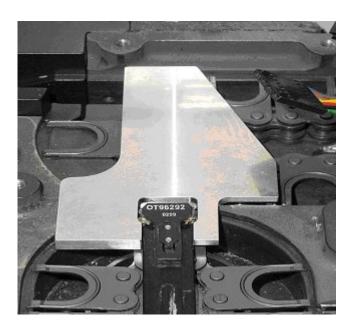


Figure 19 Back Position



Tube Lifter

Use the following list to configure the Tube Lifter module.

- *Home* Not a configurable position. You must HOME the motor prior to setting any of the positions.
- *Up* Move the tube lifter up to about 1/32" below the transfer chain baffle.
- *Down*—Lower the tube lifter to a position even with, or slightly below, the floor level of the wash station in order to avoid interfering with reaction tubes when they go through the wash station.

Configuring Tube Lifter

- **1.** Enter into Motor Configurations and go to Slave 3.
- 2. Highlight the Tube Lifter, move UP 100 steps, and click HOME.
- 3. With Auto Update turned on, the Decimal value should read approximately minus 40.
- **4.** From the HOME position, move **UP** 100 steps then in 10 step increments until the Tube Lifter just touches the baffle.
- **5.** Right-click and Save this as the **UP** Position.
- **6.** From the **UP** position move down until the Tube Lifter Shaft is just below the Incubator Casting.
- 7. Right-click and Save this as the **DOWN** position.
- **8.** Make an IML File.
- **9.** Check for spring compression of approximately .125 .250 inches (3 6 mm).

Geneva Indexer

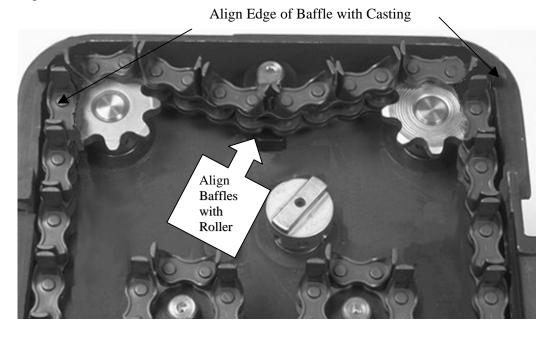
Use the following list to configure the Geneva Indexer module.

- *Home*—This position is not configurable.
- Offset—No adjustments can be made in software.

Incubator Cover Alignment Procedure

The alignment of the Incubator Cover is without question the single most important alignment on the instrument. Without proper alignment of the Incubator Top Cover, the instrument will have chronic Incubator Chain jams. The proper alignment of the Incubator Cover is an iterative process where tubes are visually checked passing in and out of the transfer positions with adjustments being made until the entrance and exit transfers are perfect. The Incubator Cover Index Alignment Pins (200510) are used to set the initial alignment from which fine-tuning can begin.

Figure 20



Remove the Incubator Chain Cover and the Transfer Chain Cover. Insure the Incubator Chain is aligned as pictured above in figure 20.

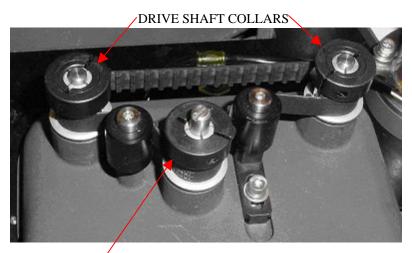
In the Diagnostic Tester, Motor Configurations mode, Slave 3, select Geneva Indexer HOME.

Place the two Alignment Pins (200510) in the first transfer position and the second transfer position of the transfer chain. Align the chain so each Alignment Pin will fit between a link in the chain without touching either side. See figure 21.

Figure 21



Figure 22



INDEXER SHAFT COLLAR

Loosen the Indexer Shaft Collar (see figure 22) and seat the Incubator Cover in the appropriate position on the tube processor. It is critical that the only collar that is ever loosened is the Indexer Shaft Collar. The two drive shaft collars should **never** be loosened. Manually turn the Indexer shaft until it aligns with the Geneva coupling. Assure that the Alignment Fixtures are still seated in the middle of the Incubator Cover Chain links before tightening the Indexer Shaft Collar. If the Alignment Fixtures are not seated correctly, then the chain drive shafts should be rotated until the fixtures are seated correctly.

PMT Attenuator

Use the following list to configure the PMT Attenuator module.

Note: Set these positions *without* a PMT installed.

- Home- Not a configurable position. You must HOME the motor prior to setting any of the positions.
- *Closed*—Move the attenuator disk so that the solid portion of the disk covers the opening to the read station.
- Attenuated—Move the attenuator disk so that the attenuator filter covers the opening to the read station.
- *Open*—Move the attenuator disk so that the open hole on the disk provides maximum viewing of the read station.

Configuring Attenuator Disk

- **1. HOME** the Attenuator Disk.
- 2. Go 100 steps CLOCKWISE.
- 3. Right-click to save "OPEN" position.
- **4.** Go 300 steps COUNTERCLOCKWISE.
- **5. Right-click** to save "ATTENUATED" position.
- **6.** Go 400 steps COUNTERCLOCKWISE.
- **7. Right-click** to save "CLOSED" position.

9.2.7 Configure Slave 4 Motors

- o Dilution Well Speed- The desired speed values are in revolutions per minute and can be changed to any value between 500 & 10,000. Speed choices are available for mixing and emptying the dilution well. The Mixing speed should be set to 1000 rpm, and the Empty speed should be set to 8300 rpm. Change the time in the seconds field to 2.0 seconds. Measure the speed of the dilution well by left clicking on the desired speed. Changing the desired speed value, then right clicking on the new value will search and record the new speed. These speeds are for diagnostic testing only, and are not used for the main operating program.
- Wash Well Speed- This is the speed of the reaction tube wash station. The desired speed for optimum bead wash is 7000 rpm. Change the time in the seconds field to 2.0 seconds. Measure the speed of the wash station by left clicking on the desired speed. Changing the desired speed value, then right clicking on the new value will search and record the new speed. These speeds are for diagnostic testing only, and are not used for the main operating program.

9.3 Unimetrics Ceramic Valve Configuration Procedure

Note: This procedure requires the use of the Ceramic Valve Configuration Fixture (200307).

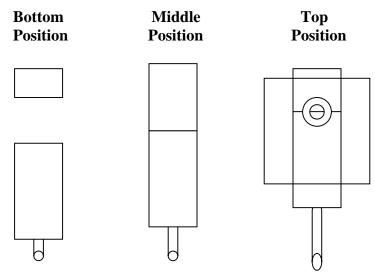
- 1. Load DIAGNOSTICS and go to the MOTOR CONFIGURATION menu.
- **2.** Select the Rotary Valve you wish to configure.
- 3. Click the HOME option in the position list. The motor will move clockwise until it finds HOME.
- **4.** Hold the configuration fixture so the pins are at the top and bottom of the valve opening.
- **5.** Rotate the shaft of the fixture until the coupling on the fixture aligns with the coupling on the motor shaft.
- **6.** Insert the fixture into the valve opening. Make sure the faceplate is firmly seated against the valve housing.
- 7. Click the HOME option in the position list. The motor will move clockwise until it finds HOME.
- **8.** Use the on-screen buttons to rotate the motor clockwise until the rollers on the fixture click into the detent grooves.
- **9.** Set this position as the rotary valve WATER position by right clicking on the position.
- 10. Carefully remove the fixture from the valve opening without turning the motor shaft.
- 11. Orient the valve to be installed so the closed port is in the upper right hand corner.
- **12.** Turn the shaft until the flat is lined up with the "Water" port on the rotary valve (lower right hand corner).
- 13. Check that the coupling on the valve now aligns with the coupling on the motor.
 - a) If the couplings align properly, the valve may be installed.
 - b) If the couplings DO NOT align properly, remove the coupling from the valve shaft and rotate it so the other set screw is located on the flat. This will now align the couplings and the valve may be installed.
- 14. Click the HOME option in the position list. The motor will move clockwise until it finds HOME.
- **15.** Click the WATER position in the position list. The motor will move clockwise until it reaches the WATER port in the lower right hand corner of the valve.
- **16.** From the WATER port, move the motor 100 steps clockwise. Set this position as the PROBE WASH port.
- **17.** From the PROBE WASH port, move the motor 100 steps clockwise. Set this position as the PIPETTE TIP port.
- 18. Click on MAKE IML FILES to create and transmit the configuration files to the Control PC.

9.4 Sample and Reagent Dilutor Configuration Procedure

The following procedure applies to both the Sample and Reagent Dilutor.

Note: If running Software Version 2.1 or higher ENABLE the "Remain Powered" feature.

- 1. Load DIAGNOSTICS and go to the MOTOR CONFIGURATION menu.
- 2. Select the Dilutor you want to configure.
 - a) The Sample Dilutor resides on Slave 0.
 - b) The Reagent Dilutor resides on Slave 1.
- 3. HOME the Dilutor, move DOWN 300 Steps, and HOME the Dilutor again.
- **4.** Manually move the Dilutor down until you reach the Mechanical BOTTOM. Move UP 120 200 steps using the software. (Look for a slight gap that will allow you to see a small portion of the silver guide bar). Right-click to save this position as your BOTTOM position.
- **5.** HOME the Dilutor. From the HOME position, begin moving DOWN until the two Ceramic Pistons just separate.
- **6.** Begin moving UP until the two Ceramic Pistons just meet. Then begin moving UP 10 steps at a time until you see the Upper Ceramic Piston just move.
- 7. Right-click to save this as your MIDDLE Position.
- **8.** From this position begin moving up until the two Ceramic Pistons are in the middle of the hole of the Port on the clear Acrylic Piece. (If you go beyond the hole begin moving back down until you are centered)
- **9.** Right-click to save this as your TOP Position.
- 10. Make an IML File.



9.5 Configurations for IMMULITE 2500

Note: This section will cover only configuration for the IMMULITE 2500 only.

9.5.1 Configure Slave 1 Modules

Note: Failure to properly home the Pipettor Arm will cause incorrect configurations

Reagent Arm Z

Use the following list to configure the new motor positions for the Reagent Arm Z.

- Test unit Position the probe so that it stops 10-15 steps above the bead in the reaction tube.
- *Holding position-* Go to the Reagent X Holding location and position the probe so that it touches the Incubator cover and go up 100 steps.
- Incubator 2 Position the probe so that it stops 10-15 steps above the bead in the reaction tube.

Reagent Arm X

Use the following list to configure the new motor positions for the Reagent Arm X.

- *Test Unit-* Align the reagent probe to be centered in the reaction tube in the pipetting position. The probe should be centered over the bead.
- *Inc 1 Holding Position* Move the reagent pipettor to a position close to the pipetting position, with out hitting the Incubator cover or the sample pipettor if it is dispensing into the reaction tube.
- *Inc 2 Pipette Position* Align the reagent probe to be centered in the reaction tube in belt 2 pipette position.
- *Inc 2 Holding Position* Move the probe so that it is centered between the Inc 2 Pipette Position and the mounting screw of the Incubator cover.

9.5.2 Configure Slave 2 Modules

Tube Transport

Use the following list to configure the Tube Transport module.

- Home—Not a configurable position. You must HOME the motor prior to setting any of the positions.
- Offset—Align the tube transport clip with the entrance to the pipetting position in the tube processor.
- O Holding—Keeps the Reaction Cup out of the way while the Processor Shuttle prepares to push the cup into Incubator 1. To configure this position: From the Offset position move the transport chain forward until the HOME Sensor turns RED. Move backwards 100 steps. Right Click to save this position.

Incubator Belt 1 Configuration

Left click on **Remain powered** to activate this feature.

The **Home** position is not configurable in diagnostics. The home sensor sees the home flag and stops. The chain will also move the extra steps set in fixed parameters after seeing the Home flag. All other positions are set after belt has been homed. The baffle that signals home is the only baffle that has a tab twice as long as the others.

Position 1 @ **Receive**: You set this position by centering the home baffle at the entrance to the Incubator. Right click on the **Position 1** @ **Receive** button to save the encoder value.

Position1 @ **Xfer**: You set this position by centering the home baffle in the location where the reaction cup is transferred from belt 1 to belt 2. Right click on **Position 1** @ **Xfer** button to save the encoder value.

<u>Note</u>: Receive CW, Receive CCW, Belt Transfer CW, and Belt Transfer CCW are all auto computed when you right click to configure the encoder values for position 1 @ these locations.

Incubator Belt 2 Configuration

Left click on **Remain powered** to activate this feature.

The **Home** position is not configurable in diagnostics. The home sensor sees the home flags and stops. The chain will also move the extra steps set in fixed parameters after seeing the Home flag. All other positions are set after belt has been homed. The baffle that signals home is the only baffle that has a tab twice as long as the other baffles.

Position 1 @ **Xfer**: Is set by centering the home baffle at the opening in the casting between the Incubators. Right click on the **Position 1** @ **Xfer** button to save the encoder value.

Position 1 @ Wash 1: Is set by centering the home baffle at the Incubator exit into the wash 1 station. Wash station 1 is the one to the left. Right click on the **Position 1** @ Wash 1 button to save the encoder value.

Position 1 @ Wash 2: Is set by centering the home baffle at the Incubator exit into the wash 2 station. Wash station 2 is the one to the right. Right click on the **Position 1** @ Wash 2 button to save the encoder value.

Position 1 @ **Pipette**: Is set by centering the home baffle under opening in the cover over Incubator belt 2. This is where the reagent is pipetted through the hole into the reaction cup. This hole is located at the back left corner of Incubator 2. Right click on the **Position** button to save the encoder value.

<u>Note</u>: Wash 1 CW Offset, Wash 1 CCW Offset, Wash 2 CW Offset, Wash 2 CCW Offset, Pipette CW, Pipette CCW Belt Transfer CW, and Belt Transfer CCW are all auto computed when you right click to set the encoder setting for position 1 @ these locations.

9.5.3 Configure Slave 3 Modules

Luminometer Belt Alignment

Left click on Remain powered to activate this feature.

The **Home** position is not configurable in diagnostics. The home sensor sees the home flag and stops. The chain will also move the extra steps set in fixed parameters after seeing the Home flag. All other positions are set after belt has been homed. The baffle that signals home is the only baffle that has a tab twice as long as the others.

Position 1 @ Wash 1: Is set by centering the home baffle at the Luminometer entrance from the wash station. Wash 1 Station is the one on the left. Right Click on the Position 1 @ Wash 1 button to save the encoder value.

Position 1 @ Wash 2: Is set by centering the home baffle at the Luminometer entrance from the wash station. Wash 2 Station is the one on the right. Right Click on the Position 1 @ Wash 2 button to save the encoder value.

Position 1 @ **Transfer**: Is set by centering the home baffle where the reaction cup is transferred into the Luminometer Disk. Right Click on the Position 1 @ Transfer button to save the encoder value.

Position 1 @ **Substrate**: Is set by centering the home baffle where the substrate probe dispenses into the reaction cup. To perform this configuration it will be necessary to install the Luminometer Cover and remove the Substrate Probe Housing. Right Click on the Position 1 @ Substrate button to save the encoder value.

<u>Note</u>: Wash 1 CW Offset, Wash 1 CCW Offset, Wash 2 CW Offset, Wash 2 CCW Offset, Transfer CW Offset, Transfer CCW, Substrate CW and Substrate CCW are all auto computed when you right click to set the encoder setting for position 1 @ locations.

Tube Lifter 1 & 2

RECEIVE TUBE:

Used to move test unit into wash station and out into the Luminometer Set Wash Station Platform level with Incubator Exit, then move down 20 steps, Right click on "RECEIVE TUBE" to save.

TRANSFER OUT:

Used to move test unit out of the wash station and into the incubator after wash From the "RECEIVE TUBE" Position, move up 40 steps. Right click on "TRANSFER OUT" to save this position.

DOWN:

From the "RECEIVE TUBE" Position go down 500 steps, Right click and save this as your "DOWN" position.

WASH TUBE:

Notes:

"Remain Powered" must be enabled.

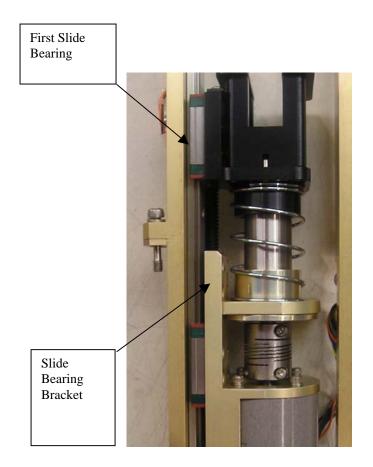
A Reaction Cup must be placed in the Wash Station prior to setting this adjustment.

- 1. Properly home the Tube Lifter in the following manner:
 - a Click "HOME"
 - **b** Move "UP" 500 steps
 - c Click "HOME"
- 2. Place a Reaction Cup into the Wash Station
- 3. Select "Remain Powered".
- 4. Begin moving the lifter UP 100 steps at a time until the first slide bearing stops moving. Once this happens, continue moving up for approximately another 600 800 steps. From this point, the slide bearing bracket will begin moving upward (see attached image). Once this slide bearing bracket stops moving (it may be necessary to move in 10 step increments to help find this point), Move up another 100 steps. Right click on "WASH TUBE" to save this position.

<u>Note</u>: Verify the Reaction Cup fully engages with upper spinner gear at the WASH TUBE position, before attempting to RUN instrument, utilizing the below method:

- 1. Move to the "WASH TUBE" Position with a reaction tube in the Wash station, if you are not already there.
- 2. Go to SLAVE-4 and spin the appropriate spinner. (This is to make sure that the tube bottom engages with the drive gear while configuring).
- 3. To ensure that we are at 100 steps move DOWN 100 steps. The slide bracket should not move.
 - If it **moves** then the configuration is less than 100 steps. Please re-do the procedure.
 - If the slide bracket **does not move** go down 10 steps more. The slide bracket should start moving now. This will ensure that the configuration is at 100 steps.
 - If it does not move then the configuration is more than 100 steps. Please re-do the procedure.

<u>Caution</u>: Failure to follow the above notes and procedure could give improper spring compression and compromised results.



Luminometer Disk

The **Home** position is configured by a physical alignment. In the back left corner there are 3 holes, by loosening the compression nut and homing the Luminometer Disk. Align the white line to the middle of the largest hole in the back. Then tighten the compression nut to 100 in/lbs.

Lum Chain: Is set by setting the opening of the Luminometer Disk so the slot for the reaction cup lines up with the opening of the casting. (The transfer seems better if the edge of the slot close to you is lined up with the edge in the casting.) This leaves the step between the casting and the far edge. Right click on the Lum Chain button to save the encoder value.

PMT Read: Is set so that the reaction cup is centered in the opening of the casting to give the best transfer of the photons. With the white line pointing at the PMT remove the screw in the top part of the Luminometer Disk. Install a small Phillips screwdriver in the hole and lock it in position. Right click on the PMT Read button to save the encoder value.

Exit Chute: Is set so that the reaction cup makes a smooth transition to the waste chute. This is done by the far edges lining up with the casting. This will allow for a smooth transition. Right click on the Exit Chute button to save the encoder value.

Lum Holding: Is set so that the opening of the reaction cup is lined up in between the exit and Luminometer Chain location. Care must be taken so the transfer point does not have any of the open area for the Luminometer Disk. If the reaction cup hits any of the open area of the Luminometer Disk it will splash at that location. Right click on the Lum Holding button to save the encoder value.

PMT Holding: Is set using the three holes in the left back of Luminometer casting. Line the white line up with the fist small screw hole moving from the Luminometer Chain towards the PMT Read position. Right click on the PMT Holding button to save the encoder value.

Cutaway: Line the leading edge of the cutout with the trailing edge of the exit slot. Right click on the Cutaway button to save the encoder value.

Attenuator Configuration

Left click on Remain powered to activate this feature.

The **Home** position is set by a sensor seeing a cutout in a disk. This position is not configurable.

Closed: Is set by turning on remain powered and moving the Attenuator Disk CCW until the inside disk touches the casting. Move the attenuator disk 3 steps CW. Right click on the **Closed** button to save the encoder value.

Attenuated: Is set by removing the PMT and moving the attenuator disk CW until the hole for the tube is centered with the attenuator mirror. Right Click on the Attenuator button to save the encoder value.

Open: Is set by moving the attenuator disk CW so the flat edge is lined up with the beginning edge of the screw toward the front the instrument holding the orifice disk in place. Right click on the **Open** button to save the encoder value.

PMT Transfer

NOTE: Removal of Luminometer Cover is necessary for this alignment

Lum Position: Is set by the sensor automatically. This is not configurable.

PMT Chamber: Is set by the sensor automatically. This is not configurable.

Steps to Sensor: Left click on the PMT Position and then on the Lum position to make sure the PMT Transfer arm has been homed. With the Luminometer Cover removed, move the arm in the 300 steps in the CW direction until the PMT Chamber indicator turns red. Right click and save this position.

Steps to chamber: Move PMT Transfer arm 10 steps at a time CCW until "PMT Chamber" Sensor turns off, then move One step at a time CW until the sensor turns RED again. Left Click on "Step Counter" to zero it out.

Move "PMT Transfer" arm CW until it touches the Luminometer Cover casting. Move CCW 20 Steps, RIGHT Click and save as "Steps To Chamber".

To verify position, move PMT Transfer arm back to LUM Position. Place a reaction tube on the Luminometer Baffle. Install Luminometer Cover and move the PMT Transfer Arm to "PMT Chamber", then back to "LUM Position". Remove the Luminometer Cover and ensure the Reaction Tube is fully

seated in the Luminometer Disk.

9.5.4 Slave 6 Configurations

Processor Shuttle Configuration

Move the shuttle 200 steps towards the incubator and then **Left Click** on **Home**. The Home indicator should turn red.

Closed: Move the shuttle all the way towards incubator 1 until the front of the shuttle lines up with the inner wall of the Incubator Cover to create a path for the Reaction Tube to pass along without causing splashing. Right click on the **Closed** button to save this encoder value.

Accept Tube: Move the shuttle back until the shuttle arm clears the Home Flag of the Transport Chain. **Right click** on the **Accept Tube** button to save this encoder value.

Incubator Belt Transfer

Move the Incubator Belt Transfer Arm 300 steps towards Incubator Belt 2, then Left Click **Home.** The Home indicator should turn red.

Middle: From the HOME position, move 130 steps toward Belt-1 (front of system). Save as "MIDDLE"

Transfer to Belt 2: From the HOME position, move the arm until it is even or flush with the incubator cover inner surface on the Belt-2 side.

Transfer to belt 1: From the HOME position, move 130 steps toward Belt-1 (front of system). Save as "Transfer to Belt-1"

Wash Transfers 1 and 2

Move the transfer toward wash station 200 steps.

Left click on the **Home** button. The arm that moves the reaction cup should move back and the **Home** indicator should turn red.

Incubator: Is set by looking at the inside of the cover, align the arm so the inside edge of the cover is flush with the inside edge of the arm. This will create a continuous smooth wall for the tube to ride against. Right click on the **Incubator** button to save the encoder value.

Wash Station: Remove the sump and place a Reaction Tube in the appropriate Incubator 2 Wash Position. Begin advancing the wash station transfer arm by clicking on the Wash station step selection area. Continue stepping forward until the Reaction Tube is centered in the detent area of the Wash Station Tube Guide. Move the arm back towards Incubator Belt 2 15 steps. Right click on the **Wash station** to save the encoder value.

Luminometer: Is set by moving the arm manually until it touches the Luminometer cover casting, then moving it back 150 steps. Right click on the **Luminometer** button to save the encoder value.

Exit Transfer Alignment Configuration

The **Home** position is not configurable in diagnostics. The home sensor sees the home flags and stops. All other positions are set after exit transfer has been homed.

PMT Chamber: Is set by homing the Exit Transfer and then moving the arm to 1/16" (1 mm) from the edge of the Luminometer Disk cutout in the cover. Right click on the **PMT Chamber** button to save the encoder value.

Exit Chute: Is set by homing the Exit Transfer and then move the arm 1/16" (1 mm) space from the casting at the exit side of the travel of the arm. Right click on the **Exit Chute** button to save the encoder value.

Chapter 10: Diagnostics

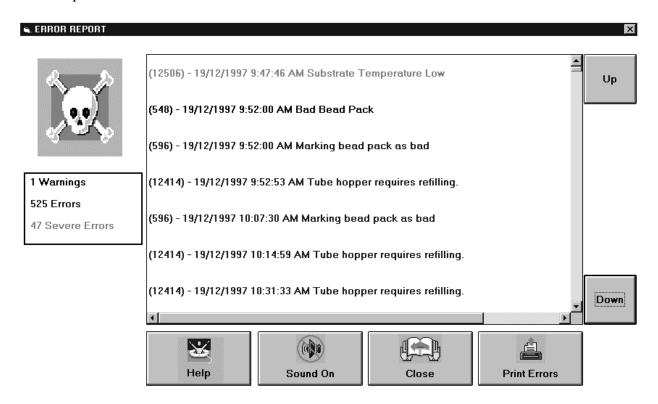
10.1 Introduction

This section provides information about the IMMULITE 2000/2500 error reporting and diagnostics.

10.2 The Error Report

The Error Report screen lists the current system errors. It appears automatically when the IMMULITE 2000/2500 detects an error. A sample Error Report is shown below:

Figure 17 Error Report screen Assistance



Note: Move the scroll bar to the right to view the end of a long error message.

The buttons on the Error Report screen are explained in the table below:

Button	Function			
Help	Gives directions for correcting the problem which caused the error.			
Sound On or Sound Off	When Sound On is selected, the system will beep when the Error screen appears. The button changes to Sound Off . When Sound Off is selected, the system will <i>not</i> beep when the Error screen appears. The button changes to Sound On .			
Close	Closes the Error screen.			
Print Errors	Prints the current errors.			

10.2.1 Viewing the Error/Event Logs

There are two Error Log screens:

- the Cumulative Event Log
 - Normal View Displays ONLY severe and non self-correcting jams that cause front-end shutdowns
 - Detailed View Displays ALL self-correcting jams in addition to content of Normal View.
- o the Daily Error Log

Cumulative Event Log

The Cumulative Event Log screen provides an event and error history. Follow the instructions below to view the Cumulative Event Log.

1. Log off the system.

The Initial screen appears (see Figures below).

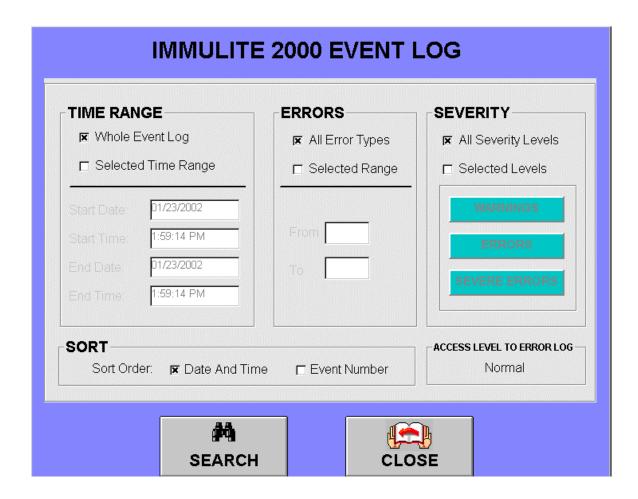
Initial screens – IMMULITE 2000 and IMMULITE 2500





- 2. Touch the View Event Log button.
 - The following screen appears, which is used to specify the type of errors to display.
- 3. Select the Normal option under Access Level to Error Log.
- **4.** Enter "c1rrus" at the password prompt. Touch the **OK** button to view the detailed error log. Cumulative Event Log Specification screen

<u>Note</u>: IMMULITE 2500 Cumulative Event Log Specification screen only difference is the title: "IMMULITE 2500 EVENT LOG"



5. Under TIME RANGE, click on Whole Event Log to view the entire error history or Selected Time Range to specify a date and time.

If Selected Time Range was chosen:

- type the desired Start Date and End Date
- o if desired, type the desired Start Time and End Time

The format for entering the date and time must be consistent with the **Date Format** and **Time Format** chosen on the Display Options screen when the system was configured.

6. Under **ERRORS**, click on **All Error Types** to view all errors or **Selected Range** to view specific errors (for example, only Pipettor Tip Jam errors).

If **Selected Range** was chosen, enter the error code number(s) corresponding to the desired error type (or types) in the **From** and **To** windows.

7. Under **SEVERITY**, click on **All Severity Levels** to view all errors or **Selected Levels** to view only a certain type of error.

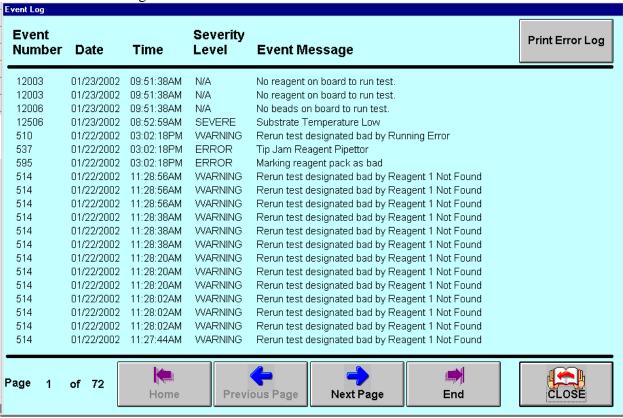
If **Selected Levels** was chosen, click on the **WARNINGS**, **ERRORS**, or **SEVERE ERRORS** button.

<u>Note</u>: More than one button can be chosen. *Severe errors* are errors which affect test results or interrupt Instrument operation.

- 8. Sort the errors by either **Date and Time** or **Error Number** by clicking the desired option at the **Sort Order** prompt.
- **9.** Touch the **SEARCH** button.

The Cumulative Event Log screen appears listing the errors which meet the criteria chosen on the Cumulative Event Log Specification screen.

Figure 20 Cumulative Event Log screen



- 10. Touch the Previous Page, Next Page, Home, and End buttons to scroll through the error messages.
- 11. Touch the **CLOSE** button to exit the Event Log.

Daily Error Log

The Daily Error Log screen shows the error messages for the current day only. Follow the instructions below to view the Daily Error Log.

1. From the drop-down menu, choose **Tools** and **View Day Error Log**. The Daily Error Log appears.

Figure 21 Daily Error Log screen

Event Number	Date	Time	Severity Level	Event Message	Print Error Log
161 107 519 524	10/31/1997 10/31/1997 10/31/1997 10/31/1997	08:58:32AM 08:58:32AM 10:28:43AM 10:28:44AM	N/A N/A WARNING WARNING	Tube indexer trying to move after jam ' LmiMoveMotor has jammed. IMMULITE 2000 doors must be closed for operation Sample Door or Main Cover is open	

2. Use the **Previous Page** and **Next Page** buttons to page through the errors.

<u>Note</u>: Touch the **Home** and **End** buttons to move to the beginning and end of the error list respectively.

3. Touch **CLOSE** to close the Daily Error Log screen.

10.3 Automatic BACKUP

When the operator logs off the system, a system backup is automatically initiated. The backup process creates a copy of the current data. If there is a major hardware problem, the current data can be restored to the system.

10.4 Diagnostics

IMMULITE 2000/2500 diagnostic programs are used to diagnose or correct system problems. After loading a program, instructions appear which are specific to that program.

Loading a Program

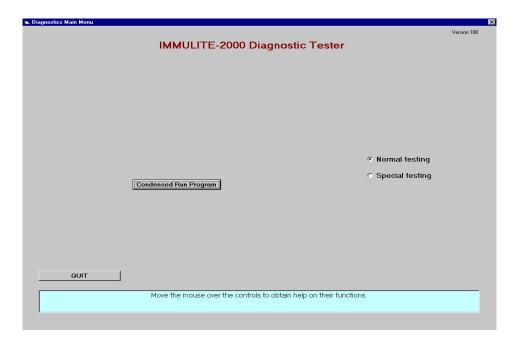
Follow the instructions below to load a diagnostic program.

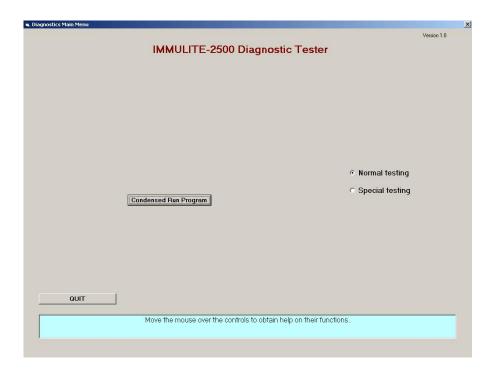
1. Log off the system.



2. Double-click on the **Diagnostics** icon Diagnostics. The following screen appears:

Figure 22
Diagnostics Main Menu for IMMULITE 2000 and IMMULITE 2500

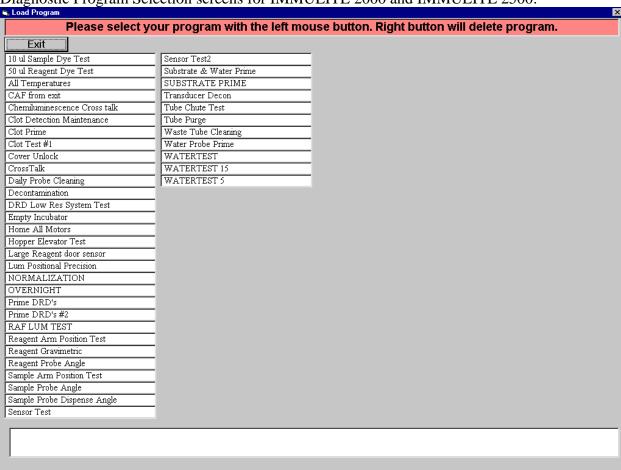




3. Click on the Condensed Run Program button.

The Diagnostic Program Selection screen appears.

Figure 23
Diagnostic Program Selection screens for IMMULITE 2000 and IMMULITE 2500:







- **4.** Select the desired program by clicking on the program name with the left trackball button.
- **5.** Click on the **RUN** button.

Prompts appear with instructions specific to this diagnostic program.

<u>Note</u>: If the program stops automatically, click on the **Exit** button. If the program does *not* stop automatically, click on the **Stop** button and then click on the **Exit** button.

Program Description

The diagnostic programs for the IMMULITE 2000 are listed and described in the table below:

Program Name	Description	
10 uL Sample Dye Test	Used to evaluate the pipetting precision of a 10uL sample volume.	
	Before running this program, the Home All Motors diagnostic program must be run.	
50 uL Reagent Dye Test	Used to evaluate the pipetting precision of a 50uL reagent volume.	
	Before running this particular program, the Home All Motors diagnostic program must be run.	
All Temperatures	Displays the current temperatures of the Incubator, Luminometer, Substrate Heater, and Reagent Carousel (in this order) in a small green window at the bottom right corner of the screen.	
APB WT 5	This program is used during manufacturing.	
CAF from exit	This program is used during manufacturing.	
Chemiluminescence Cross talk	This program is used in manufacturing qualification testing of the luminometer of the IMMULITE 2000. It requires the use of two special constant light emitting reaction tubes.	
Clot Detection Maintenance	This program will drain the pressure transducer through the Sample Probe, then prime the pressure transducer through the Sample Probe. This is to help remove any occlusions within the clot detection section that may cause false clot detection.	
Clot Prime	Used to prime the Clot Transducer Cavity.	
	<u>Note</u> : This program does not prime the entire fluidics system.	
Clot Test #1	This program is used during manufacturing.	
Cover Unlock	Tests Instrument cover's latch mechanism.	
CrossTalk	This program is used during manufacturing.	
Daily probe cleaning	Used to carry out the daily probe cleaning maintenance routine for both the Sample and Reagent Probes. The following components are required: DPC Cleaning Solution, a sample tube, and a special Reagent Wedge.	
Decontamination	Used to carry out a decontamination routine using probe wash (prepared 10X dilution) in the Water and Probe Wash lines.	
	Prior to running the decontamination program, the Home All Motors diagnostic program must be run. Once this is complete, load Decontamination and follow instructions which appear on the screen.	
DRD Low Res System Test	This program is used during manufacturing.	
Empty Incubator	This program is used during manufacturing.	

Home All Motors	Used to initialize the motors before running the Dye Test and Decontamination diagnostic programs.	
Hopper Elevator Test	Moves the Hopper Elevator and tests the elevator sensor.	
Large Reagent door sesnsor	Tests sensor of larger door on Reagent Carousel.	
Lum Positional Precision	This program is used during manufacturing.	
NORMALIZATION	This program is used during manufacturing.	
OVERNIGHT	This program is used during manufacturing.	
Prime DRD's	Primes most of the fluidics lines (Water and Probe Wash) with the exception of the Transducer and the Water Probe.	
Prime DRD's # 2	Uses the same priming sequence as "Run IMMULITE."	
RAF LUM TEST	This program is used during manufacturing.	
Reagent Arm Position Test	Moves and pauses the Reagent Probe Arm at each of its pipetting positions.	
Reagent Car Position Test	Moves to various Reagent Carousel positions.	
Reagent Gravimetric	Reagent Gravimetric Program (50 uL – 100 uL).	
Reagent Probe Angle	Used to check the fluid dispensing from the Reagent Probe. The Reagen Probe is positioned over the Reagent Pipettor Drain and fluid is dispense	
	Watch the angle of the fluid dispensing from the probe. The fluid should dispense straight down from the probe in a solid stream.	
Sample Arm Position Test	Moves and pauses the sample probe arm at each of its pipetting positions.	
Sample Carousel Position Test	Moves to various Sample Carousel positions.	
Sample Probe Angle	Used to check the fluid dispensing from the Sample Probe. The Sample Probe is positioned over the Sample Pipettor Drain and the fluid is dispensed.	
	Watch the angle of the fluid dispensing from the probe. The fluid should dispense straight down from the probe in a solid stream.	
Sample Probe Dispense Angle	The Sample Probe is centered over the Blind Hole, high enough that the stream coming from the tip is visible. The customer should then watch the angle of fluid dispensing from the probe. The angle of the fluid stream should be less than 3.5 degrees.	
Sensor Test	Tests all opto sensors in the Instrument.	
Sensor Test2	Tests all sensors, the Tube Shaker Motor, and the Hopper Elevator Motor.	
	Prior to running this program, the Home All Motors diagnostic program must be run	

Substrate & Water Prime	Instructs the operator to remove the Substrate and Water Probes from the Bead/Tube Wash Station before each is primed.	
SUBSTRATE PRIME	Primes the Substrate Probe.	
	Note: The Substrate Probe must be removed from the Bead/Tube Wash Station before priming.	
Transducer Decon	Used to carry out a decontamination routine using 0.1M NaOH in a 12 x 75mm sample tube.	
	Note: A prompt will appear to fill a sample tube with 2.5 mL 0.1M Sodium Hydroxide. This tube must be placed in position A-1.	
	<u>CAUTION</u> : In its solid form, Sodium Hydroxide is caustic. When using a Sodium Hydroxide solution, avoid contact with skin or clothing. With either the solid or the solution, take customary laboratory precautions.	
Tube Chute Test	Ensures that the opto sensor for the solid waste exit chute s functioning normally.	
Tube Purge	Empties all reaction tubes from the tube queue chute.	
	Prior to running this program, Home All Motors diagnostic program must be run.	
Waste Tube Cleaning	Cleans the wash area and associated tubing.	
Water Probe Prime	Primes the Water probe.	
	Note : The Water probe must be removed from the Bead/Tube Wash Station before priming.	
Water Test PM	This program is an automated Watertest 5. Allowing the ability to test various areas of the IMMULITE for contamination.	
WATERTEST	Used to test the water for contamination.	
	Note: WATERTEST uses two Reaction Tubes.	
WATERTEST15	Used to test the water for contamination.	
	<u>Note</u> : WATERTEST uses <i>fifteen</i> Reaction Tubes.	
WATERTEST5	Used to test the water for contamination.	
	Note: WATERTEST uses <i>five</i> Reaction Tubes.	

Program Description

The diagnostic programs for the IMMULITE 2500 are listed and described in the table below:

Program Name	Description	
IMM 2500 All Temperatures	Displays the current temperatures of the Incubator, Luminometer, Substrate Heater, and Reagent Carousel (in this order) in a small green window at the bottom right corner of the screen.	
IMM 2500 CAF	This program is used during manufacturing to calculate the blocking power of the attenuator.	
IMM2500 Clot Prime	Used to prime the Clot Transducer Cavity.	
	<u>Note</u> : This program does not prime the entire fluidics system.	
IMM 2500 Clot Test	This program is used during manufacturing.	
Daily probe cleaning	Used to carry out the daily probe cleaning maintenance routine for both the Sample and Reagent Probes. The following components are required: DPC Cleaning Solution, a sample tube, and a special Reagent Wedge.	
IMM 2500 Decontamination	Used to carry out a decontamination routine using probe wash (prepared 10X dilution) in the Water and Probe Wash lines.	
	Prior to running the decontamination program, the Home All Motors diagnostic program must be run. Once this is complete, load Decontamination and follow instructions which appear on the screen.	
IMM 2500 DRD Low Res System Test	This program is used during manufacturing.	
IMM 2500 Home All Motors	Used to initialize the motors before running the Dye Test and Decontamination diagnostic programs.	
IMM 2500 Large Reagent door sensor	Tests sensor of larger door on Reagent Carousel.	
IMM 2500 Prime DRD's	Primes most of the fluidics lines (Water and Probe Wash) with the exception of the Transducer and the Water Probe.	
IMM 2500 IMM 2500 Reagent Arm Position Test	Moves and pauses the Reagent Probe Arm at each of its pipetting positions.	
IMM 2500 Reagent Probe Angle	Used to check the fluid dispensing from the Reagent Probe. The Reagent Probe is positioned over the Reagent Pipettor Drain and fluid is dispensed.	
	Watch the angle of the fluid dispensing from the probe. The fluid should dispense straight down from the probe in a solid stream.	
IMM 2500 Sample Arm Position Test	Moves and pauses the sample probe arm at each of its pipetting positions.	

Program Name	Description	
IMM 2500 Sample Probe Angle Wash	Used to check the fluid dispensing from the Sample Probe. The Sample Probe is positioned over the Sample Pipettor Drain and the fluid is dispensed.	
	Watch the angle of the fluid dispensing from the probe. The fluid should dispense straight down from the probe in a solid stream.	
IMM 2500 Sample Probe Angle Blind	The Sample Probe is centered over the Blind Hole, high enough that the stream coming from the tip is visible. The customer should then watch the angle of fluid dispensing from the probe. The angle of the fluid stream should be less than 3.5 degrees.	
IMM 2500 Sensor Test	Tests all opto sensors in the Instrument.	
IMM 2500 SUBSTRATE	Primes the Substrate Probe.	
PRIME	Note: The Substrate Probe must be removed from the Bead/Tube Wash Station before priming.	
IMM 2500 TIP Inc1 Inlet test	Checks alignment of the TIP sensor. The target is a well-centered sensor with at least +/- 5 steps.	
IMM 2500 TIP Inc2 Belt Xfer test	Checks alignment of the TIPS sensor. The target is a well-centered sensor with at least +/- 5 steps.	
IMM 2500 TIP Inc2 Pipette test	Checks alignment of the TIP sensor. The target is a well-centered sensor with at least +/- 5 steps.	
IMM 2500 TIP Inc2 Wash 1 test	Checks alignment of the TIP sensor. The target is a well-centered sensor with at least +/- 5 steps.	
IMM 2500 TIP Inc2 Wash 2 test	Checks alignment of the TIP sensor. The target is a well-centered sensor with at least +/- 5 steps	
IMM 2500 TIP Lum Wash 1 test	Checks alignment of the TIP sensor. The target is a well-centered sensor with at least +/- 5 steps	
IMM 2500 TIP Lum Wash 2 test	Checks alignment of the TIP sensor. The target is a well-centered sensor with at least +/- 5 steps.	
IMM 2500 Transducer Decon	Used to carry out a decontamination routine using 0.1M NaOH in a 12 x 75mm sample tube.	
	Note: A prompt will appear to fill a sample tube with 2.5 mL 0.1M Sodium Hydroxide. This tube must be placed in position A-1.	
	<u>CAUTION</u> : In its solid form, Sodium Hydroxide is caustic. When using a Sodium Hydroxide solution, avoid contact with skin or clothing. With either the solid or the solution, take customary laboratory precautions.	
IMM 2500 Waste Tube Cleaning	Cleans the wash area and associated tubing.	

Program Name	Description	
IMM 2500 Water Pump volume check	Utilized to check the volumes of each of Wash Station water pumps.	
IMM 2500	Used to test the water for contamination.	
WATERTEST	Note: WATERTEST uses two Reaction Tubes.	
IMM 2500 DAQ Test 1	Used to show Wash Station 1 spin speed.	
IMM 2500 DAQ Test 2	Used to show Wash Station 2 spin speed.	
IMM 2500 Home Fluidics	Initializes all motors used to pipette fluidics.	
IMM 2500 Light Leaks	Used to evaluate if CPS increases when flashlight shines on the Luminometer near the PMT.	
IMM2500 SensorTest MNF	Prompts to block sensors as the system runs through the program.	

Chapter 11: Troubleshooting

11.1 Background

This section is designed to help in the fast, accurate diagnosis of IMMULITE 2000/2500 problems. While IMMULITE 2000/2500 repairs can be made by many people, accurate troubleshooting is a rare skill for both the experienced and the inexperienced service technician.

In its simplest state, troubleshooting is an exercise in logic. It is essential to realize that the IMMULITE 2000/2500 is really composed of a series of modules. Some of these modules are interrelated; others are not. The instrument operates within a framework of logical rules and physical laws, and the key to troubleshooting is to have a good understanding of all of the IMMULITE 2000/2500 modules.

11.2 Specimen-Processing Errors

Specimen-processing errors that an operator may experience are divided into the following categories:

Lack of Required Information

These errors include unreadable barcodes and the absence of information about which tests to run or how to run them. Whenever the Specimen Carousel is accessed, the instrument verifies the availability of all required information. If any information is lacking, the operator is alerted immediately. Thus, operators can expect the instrument to process all on-board specimens before requiring their further attention.

Sample-specific Fluidics Problems

These errors include insufficient sample or the presence of a clot. Operators are alerted immediately of such problems via both on-screen and audible alarms. However, the instrument continues to process other specimens while awaiting operator intervention.

Hardware Problems

These errors include Fluidics component failures, clogged inlet filters, etc. Operators are alerted immediately of such problems via both on-Screen and audible alarms. Until the operator intervenes, sampling operations are suspended, but Tube Processor operations continue.

11.3 Troubleshooting Techniques

One of the keys in diagnosing a problem is information. The following are questions to ask the operator (or yourself, if you are experiencing a problem) in an attempt to draw the proper information needed for troubleshooting.

1. What is the instrument serial number?

This permits positive identification of the instrument. Once the serial number is known, the instrument's age and history can be found.

2. Which version of the software is the customer using?

This is a very important question, especially during periods when the software is in the process of being updated. Certain assumptions are made about the operation of an instrument with a particular software version. Do not make these assumptions until you determine which version of the software version is being used. Using an old version of software may be the cause of the problem; updating to the new software may be the solution.

3. What is the exact nature of the problem?

Try to determine exactly what is wrong rather than just accepting the statement, "It's broken," from the operator. If you can determine exactly what is wrong, you may be able either to solve the problem over the phone or to know which part is needed for the repair when visiting the site.

4. When did the problem first appear?

If you can determine when the problem first occurred, you will be able to associate that problem with an event. Or, if the customer says that the instrument has always behaved this way (which is unusual, but not impossible), the problem could be with a procedure the operator follows incorrectly every time the instrument is used. If you can determine the first occurrence, you can then try to associate an event with the problem by asking the next question.

5. Was anything unusual done to the instrument just before the problem occurred? In many cases, the answer to this question points to the cause of the problem.

6. Is the problem reproducible?

If the problem is reproducible, it can be considered a "phone-confirmed problem" and then steps can be taken to rectify it. A phone-confirmed problem does not necessarily mean it is one that involves an instrument problem; it could as easily be a procedural problem. For example, if the operator complains of "Reagent Carousel Temperature High" errors for five minutes every morning, the problem is most likely that the lid of the Reagent Carousel Housing has been left open for a long time. If the problem is not reproducible, it may be a one-time event. Although such events are rare, they do happen. It is wise to be very persistent in reproducing or confirming a problem before determining it to be a one-time event. Remember: this one-time event could be a generous warning of an impending failure.

7. Is the instrument making any unusual sounds?

If the problem is mechanical in nature, chances are good that it is accompanied by a sound that is different from its normal sound. When an operator works with the instrument for a while, he or she learns to recognize the "normal" sound. A seemingly insignificant change in the normal sound of the instrument could be a vital clue in diagnosing the problem.

- **8.** At what point in the run does the sound occur?
 - The answer to this question will indicate if the problem is related to something (Reaction Tubes, sample cups, Reagent wedges, water, etc.) entering a section of the instrument. If the problem is mechanical, the answer can also indicate the location of the problem. That is, the location of the components can be mapped, based on when the problem occurred. For example, if the instrument has a shuttle Carousel error immediately after the instrument starts to run after being shut down, the problem is not caused by any components entering the system. In this case, the cause of the problem is probably improper shutdown, leaving the shuttle improperly positioned for initialization.
- 9. If the instrument is down, have the operator leave the instrument "as is." Many valuable diagnostic clues are left behind when an instrument has had a problem. If the operator cleans up the instrument in preparation for the arrival of a field service person, he or she may be removing these clues. (Of course, some things, such as samples and reagent vials, must be removed and refrigerated to prevent degrading.) For example, the problem is that the Reaction Tubes have been jamming the Incubator. The customer has left the instrument in the jammed condition while waiting for the arrival of the field service person. Since the field service person can see in the Incubator where the jam occurred and the condition of the jammed tube, he/she can quickly determine the cause of the jam.

11.4 Before Visiting the Customer

If the field service person must visit the customer site, the following steps will make for an efficient troubleshooting and/or repair session.

- 1. Before visiting the customer, try to duplicate the problem at the office.

 If the problem can be duplicated on an instrument at the field service office, in most cases so can the solution. This can make for a smoother and quicker repair, since the repair procedure has been rehearsed and the necessary parts have been brought on the service visit.
- 2. If the solution to the problem is not clear, create a diagnostic plan before arriving at the site. Generally, when the field service person arrives, the customer asks what could be causing the problem and how long it will take to repair. A clear, definitive answer will put the customer at ease and give him or her confidence in the repair process. This clear, definitive answer can only be the result of a well-thought-out plan of diagnosing the problem. This plan should contain all possible causes of the problem and methods used to check for each one. It should also contain a brief history of the instrument, including age, past problems, dates of any modifications, and current revision status.

11.5 At the Customer's Site

If the field service person is already examining the instrument and has completed the above steps, the following steps will help in diagnosing and resolving the problem:

1. Upon arrival at the customer's site, observe the condition of the instrument and its surroundings. The condition of the instrument could be either the cause of the problem or a contributing factor. The environment of the instrument could also be the cause of the problem or a contributor. For example, if the System is having intermittent "Electrical Ambient High" errors, the cause of the problem could be a high laboratory temperature or another instrument located behind the IMMULITE 2000/2500, exhausting warm air onto the back of the instrument. If the environment is the cause of the problem, but is never considered a possibility, the problem may never be solved.

2. If possible, duplicate or verify the problem BEFORE DIAGNOSING OR REPAIRING!

A very common mistake in repairing anything is to begin to diagnose—or, even worse—to repair a problem without first trying to duplicate or verify it. In many cases, the information that the customer supplies about the problem is not very precise, so that the service person follows the wrong path in trying to correct the problem. Worse yet is to repair (replace a part, make an adjustment, etc.) a problem without knowing if the repair is really necessary. Occasionally, there may not be a reasonable way of duplicating a particular problem; these are the most difficult problems to diagnose.

3. Check the Event Log file.

The Event Log file may contain information that the customer has not noticed. Check this file at the beginning of the diagnosing process to obtain more information about a problem.

- **4.** Do not ignore the obvious!
 - Never assume that the solution to a problem is complex. Most problems are easily diagnosed and repaired.
- **5.** When the problem is found and fixed, check the area around the problem to insure that no other problems have been created by the repair.
 - Most of the components in the IMMULITE 2000/2500 are located close together and interact with other assemblies. Therefore, during the repair process, it is possible to cause another problem while repairing the one you are diagnosing. Always check, both visually and via diagnostics, that all components around the problem area are functioning properly after the repair work is complete.
- **6.** Unless unusual circumstances exist, run controls to check the instrument. This step is necessary to determine if the repair is truly successful and that no other problems exist.

11.6 Technical Assistance

For technical questions concerning the IMMULITE 2000/2500 System, call DPC Instrument Systems Division, Inc. Technical Services at the telephone number below:

Note: If you are located outside the United States, contact your National Distributor.

DPC Instrument Systems Division A subsidiary of Diagnostic Products Corporation 62 Flanders-Bartley Road Flanders, NJ 07836

Tel: (800) 372-1782 or (973) 927-2828

Fax: (973) 927-4101

Chapter 12: Spare Parts List

12.1 Spare Parts List

Generally, before traveling to an IMMULITE 2000/2500 site to replace a part, it should be known which part(s) will be needed. However, there have been situations when the part that would have fixed the problem was either incorrect or not on hand. (A few situations have occurred where a service person has been in the vicinity of a "down" Instrument but did not have the correct part to make a speedy repair.) If this is the case, when the service person is far away from the office, it could mean many more hours or possibly another day of down time. Based on the experience of IMMULITE 2000/2500 service personnel around the world, a list of parts to have on hand when responding to a trouble call has been developed. Although some parts on the list have never failed, they should be carried since they take up little space but are critical to Instrument operation.

A partial list of IMMULITE 2000/2500 spare parts is provided in the following table.

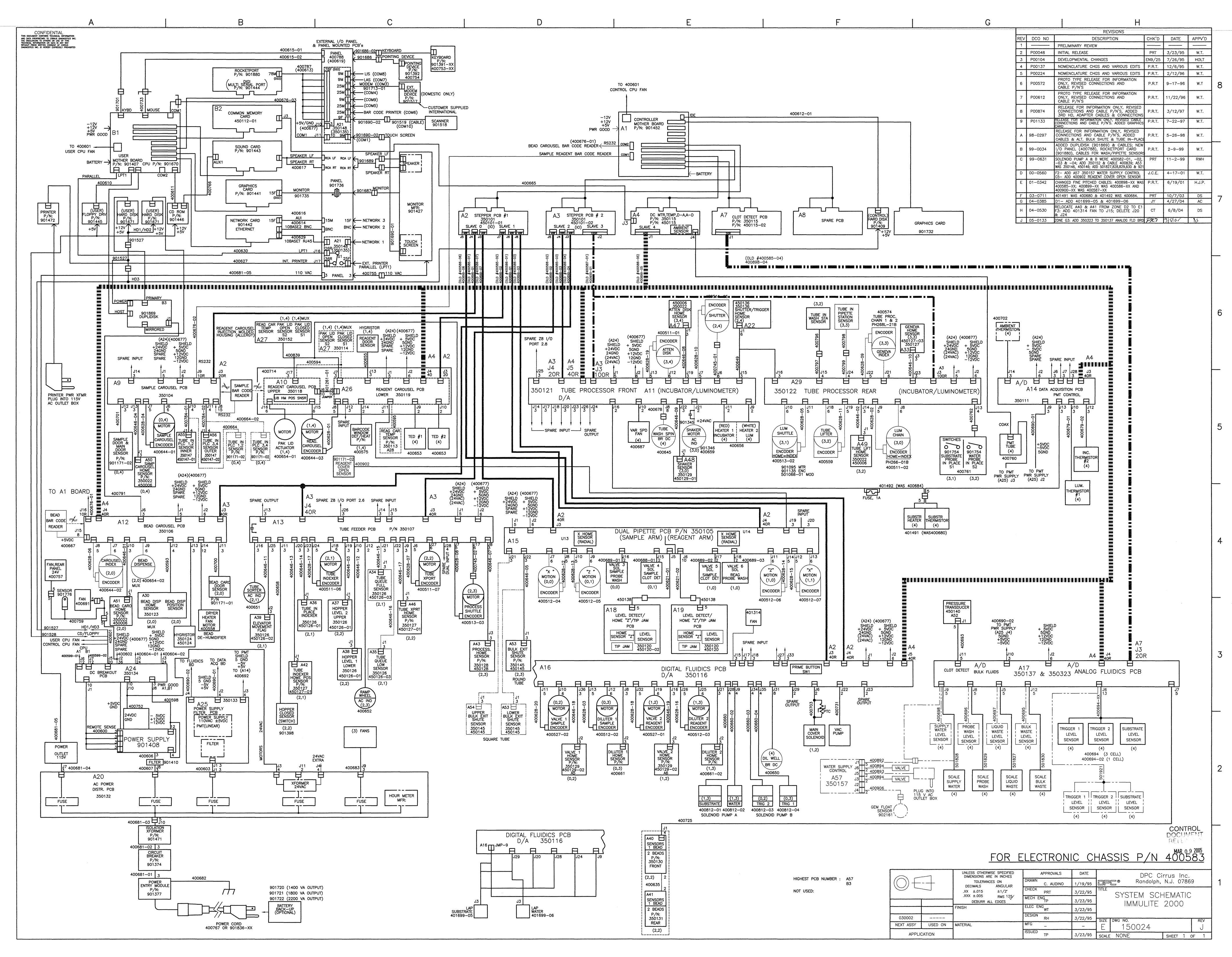
PART NUMBER	DESCRIPTION	QUANTITY	PRODUCT
400537	PROBE ASSEMBLY	2	BOTH
400637	REAGENT MANIFOLD BLOCK	1	BOTH
400653	THERMOELECTRIC DEVICE (TED)	2	BOTH
400680	SUBSTRATE HEATER ASSEMBLY	1	BOTH
400703	COVER SOLENOID ASSMEBLY	1	BOTH
400714	REAGENT CAROUSEL PCB (UPPER & LOWER)	1	BOTH
400731	VACUUM PUMP ASSEMBLY	1	BOTH
400856	HIGH SPEED SPINNER ASSEMBLY	1	2000
400869	TUBE LIFTER SHAFT	1	2000
400874	SAMPLE MANIFOLD BLOCK	1	BOTH
400916	TEMP. SENSOR & HOME POSITION /PACK LID PCB	1	BOTH
401238	ATX POWER SUPPLY W/CABLES	1	2500
401368	WASH STATION ASSEMBLY	1	2500
401378	SUMP ASSEMBLY	1	2500
401381	LITTTON DRIVER ASSEMBLY	1	2000
401447	ATX - POWER SUPPLY WITH CABLES	1	2500
401452	VACUUM PUMP ASSEMBLY #2	1	2500
401455	HIGH SPEED SPINNER MOTOR	1	2500
401458	FLUIDICS TUBING KIT (UPCHURCH)	1	2500
401536	WASH TRANSFER ASSEMBLY	1	2500
401537	BELT TRANSFER ASSEMBLY	1	2500
420022	HARDWARE KIT	1	BOTH
422035	PM KIT 2000	1	2000
422038	CERAMIC VALVE UPGRADE KIT	2	BOTH
422039	TUBE AT PIPETTE STATION	2	BOTH
422312	PM KIT 2500	1	2500
450104	SAMPLE CAROUSEL PCB	1	BOTH
450105	DUAL PIPETTE PCB	1	BOTH
450106	BEAD CAROUSEL PCB	1	BOTH
450111	DATA AQUISITON PCB	1	BOTH

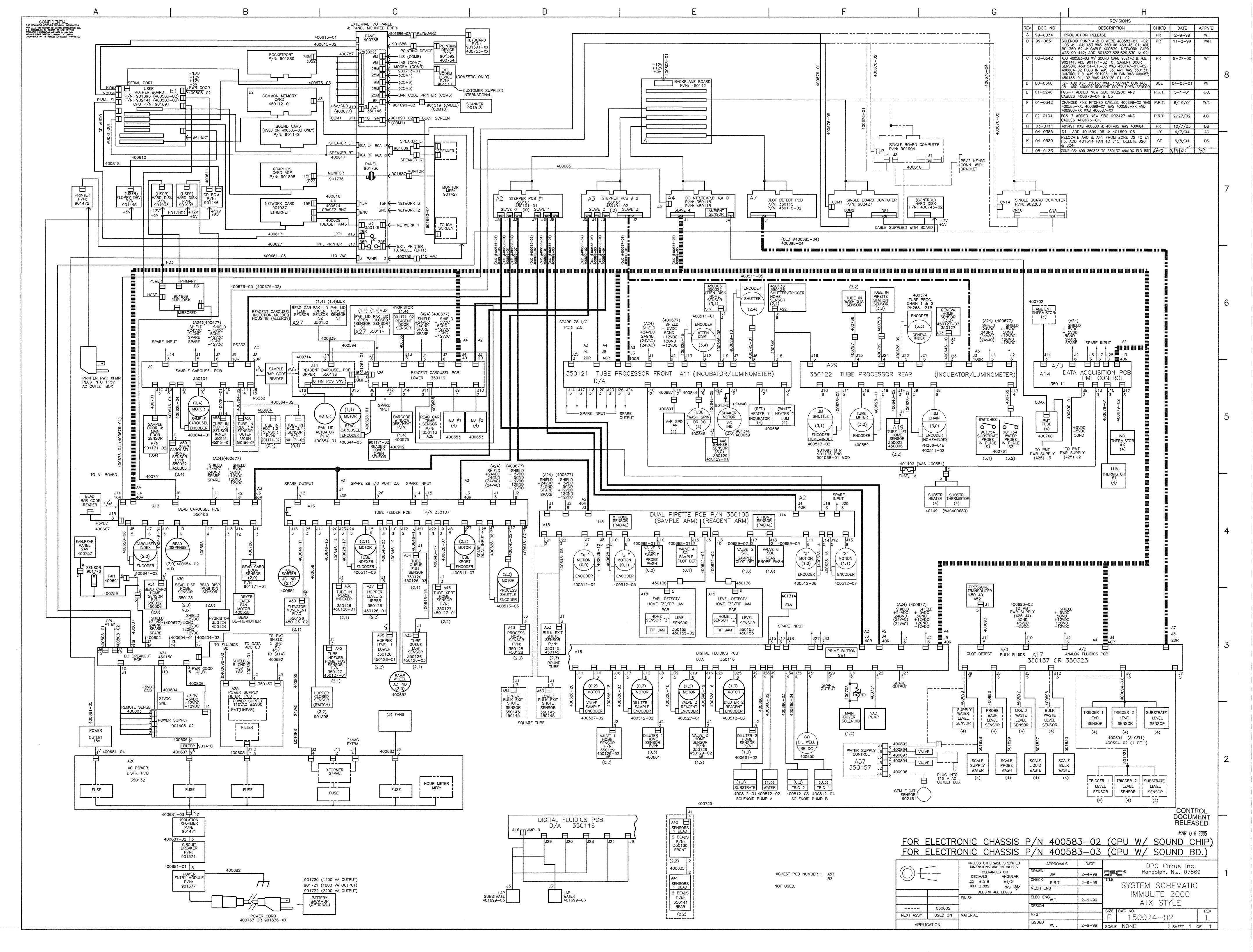
PART NUMBER	DESCRIPTION	QUANTITY	PRODUCT
450113	REAGENT TEMPERATURE SENSOR PCB (B001-	1	BOTH
	E0816)		
450114	LIEAR MOTOR SENSOR PCB (REAGENT COVER)	1	BOTH
450115	DC MOTOR/TEMP CONTROL PCB (SLAVE 4)	1	2000
450116	DIGITAL FLUIDIDCS PCB	1	BOTH
450121	FRONT TUBE PROCESSOR PCB	1	2000
450122	REAR TUBE PROCESSOR PCB	1	2000
450123	LINEAR MOTOR SENSOR PCB (BEAD DISP.)	1	BOTH
450124	HUMIDITY SENSOR PCB	1	BOTH
450134	DC PROWER DISTRIBUTION PCB - AT CHASSIS	1	2000
450137	ANALOG FLUIDICS PCB	1	BOTH
450152	REAGENT TEMP/PACK LID OPENER SENSOR PCB	1	BOTH
450159	TEMPERATURE/CLOT DETECTION PCB (SLAVE 4/5)	1	2500
450186	HOME SENSOR	4	BOTH
450187	LUMINOMETER DISK DRIVER PCB	1	2500
450188	DC POWER DISTRIBUTION PCB - ATX CHASSIS	1	2500
450195	INTERFACE PCB	1	2500
450196	LUMINOMETER PCB	1	2500
450197	INCUBATOR PCB	1	2500
450261	TAB SENSOR	3	2500
500912	DILUTION INSERT TUBE	2	BOTH
501015	DETENT DISK	1	2000
501016	DETENT GASKET (FOR DETENT DISK)	2	2000
501603	DRD COMPRESSION SPRING	2	BOTH
503781	PVC WASH STATION DRAIN TUBE ASSEMBLY	2	2500
901177	SAMPLE/REAGENT BARCODE READER	1	BOTH
901205	IN LINE FIFLER, FLUID	10	BOTH
901317	CAM FOLLOWER BEARING	1	2000
901782	CORRUGATED WASTE TUBE	2	BOTH
902145	DRD SEAL (LOWER)	2	BOTH
902146	DRD SEAL (UPPER)	2	BOTH
902217	COMPRESSION NUT (LUM DISK/BELT & INC BELTS	1	2500
902466	SERIAL CARD (SMS COM)	1	BOTH
902842	POWER SUPPLY (NO CABLES)	1	BOTH
10-900691-01	DRAIN TUBING 3/8"	1	BOTH
10-900691-02	DRAIN TUBING 1/2"	1	BOTH
20-500902-01	BAFFLE (LUMINOMETER CHAIN)	1	2000
20-500902-02	BAFFLE (TRANSFER CHAIN IN INCUBATOR)	1	2000
20-501457	CHAIN SIDE LINK	1	BOTH
20-501458	CHAIN ROLLER	1 1	BOTH
2-450006	OPTO SENSOR	1 1	BOTH
2-450006	OPTO SENSOR	1 1	2000
400621-01	SPIRAL CABLE ASSEMBLY SAMPLE PIPETTOR	1	BOTH
400621-01	SPIRAL CABLE ASSEMBLY REAGENT PIPETTOR	1	BOTH
400865-02	ATX POWER SUPPLY W/CABLES	1 1	2000
400885-01	TUBE-IN-PLACE SENSOR ASSEMBLY (INNER)	1	BOTH
400885-02	TUBE-IN-PLACE SENSOR ASSEMBLY (OUTER)	1 1	BOTH
	FLUIDICS TUBING KIT (UPCHURCH)	1	
400932-02	,	3	2000 2500
401554-01	TIP SENSOR (INCUBATOR)	3	
401554-02	TIP SENSOR (INCUBATOR)	1	2500
401829-01	INCUBATOR BELT MOTOR	1 1	2500

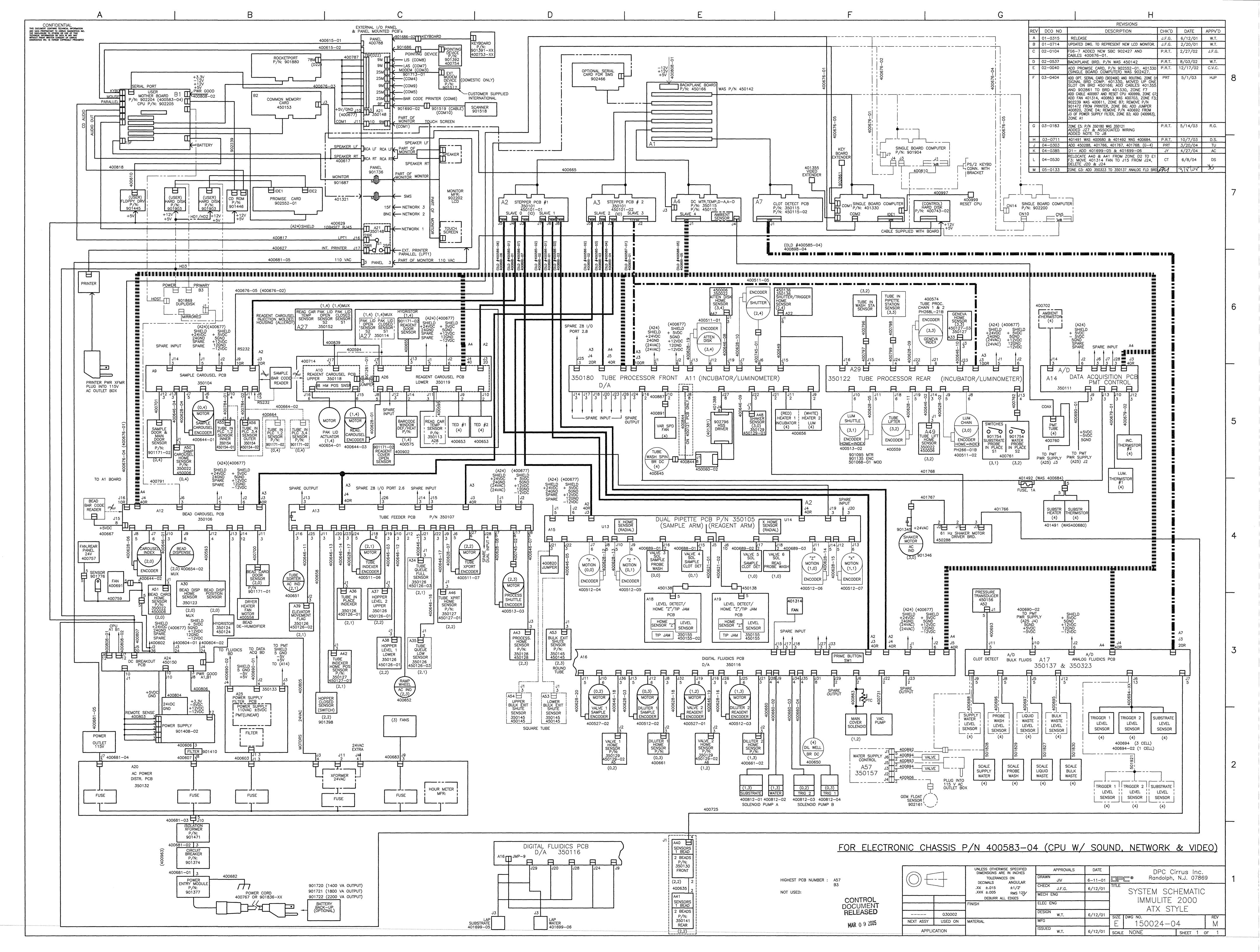
PART NUMBER	DESCRIPTION	QUANTITY	PRODUCT
401829-02	LUMINOMETER BELT MOTOR	1	2500
401833-01	INCUBATOR TRANSFER MOTOR	1	2500
422108-01	SAMPLE DRD ASSEMBLY	1	BOTH
422108-02	REAGENT DRD ASSEMBLY	1	BOTH
450101-01	STEPPER MOTOR #1 PCB (SLAVE 0/1)	1	BOTH
450101-02	STEPPER MOTOR #2 PCB (SLAVE2/3)	1	BOTH
450101-03	STEPPER MOTOR #3 PCB (SLAVE 6)	1	2500
450112-01	COMMON MEMORY PCB	1	BOTH
450115-02	CLOT DETECTION PCB	1	2000
450120-03	SHIELDED REAGENT LEVEL SENSE PCB	1	2000
450120-04	SHIELDED SAMPLE LEVEL SENSE PCB	1	2000
450155-01	REAGENT LEVEL SENSE PCB (METAL ARM)	1	BOTH
450155-02	SAMPLE LEVEL SENSE PCB (METAL ARM)	1	BOTH
502689-01	BELT CLIP	5	2500
502689-02	BELT CLIP WITH HOME TAB	3	2500
5-900133-05	TUBE LIFTER RETAINING CLIP	1	2000
5-900236-04	FUSE (1/2 AMP)	1	BOTH
5-900236-06	FUSE (1 AMP)	1	BOTH
5-900236-09	FUSE (2 AMP)	1	BOTH
5-900236-14	FUSE (5 AMP)	1	BOTH
5-900236-19	FUSE (10 AMP)	1	BOTH
5-900236-21	FUSE (15 AMP)	1	BOTH
5-902236-19	FUSE (6 AMP)	1	BOTH
900734-15	E-CLIP FOR LEAD SCREW	2	BOTH
901171-02	TUBE SENSOR (INNER AND OUTER SAMPLE)	2	2000
901408-02	MAIN POWER SUPPLY - ATX CHASSIS	1	BOTH

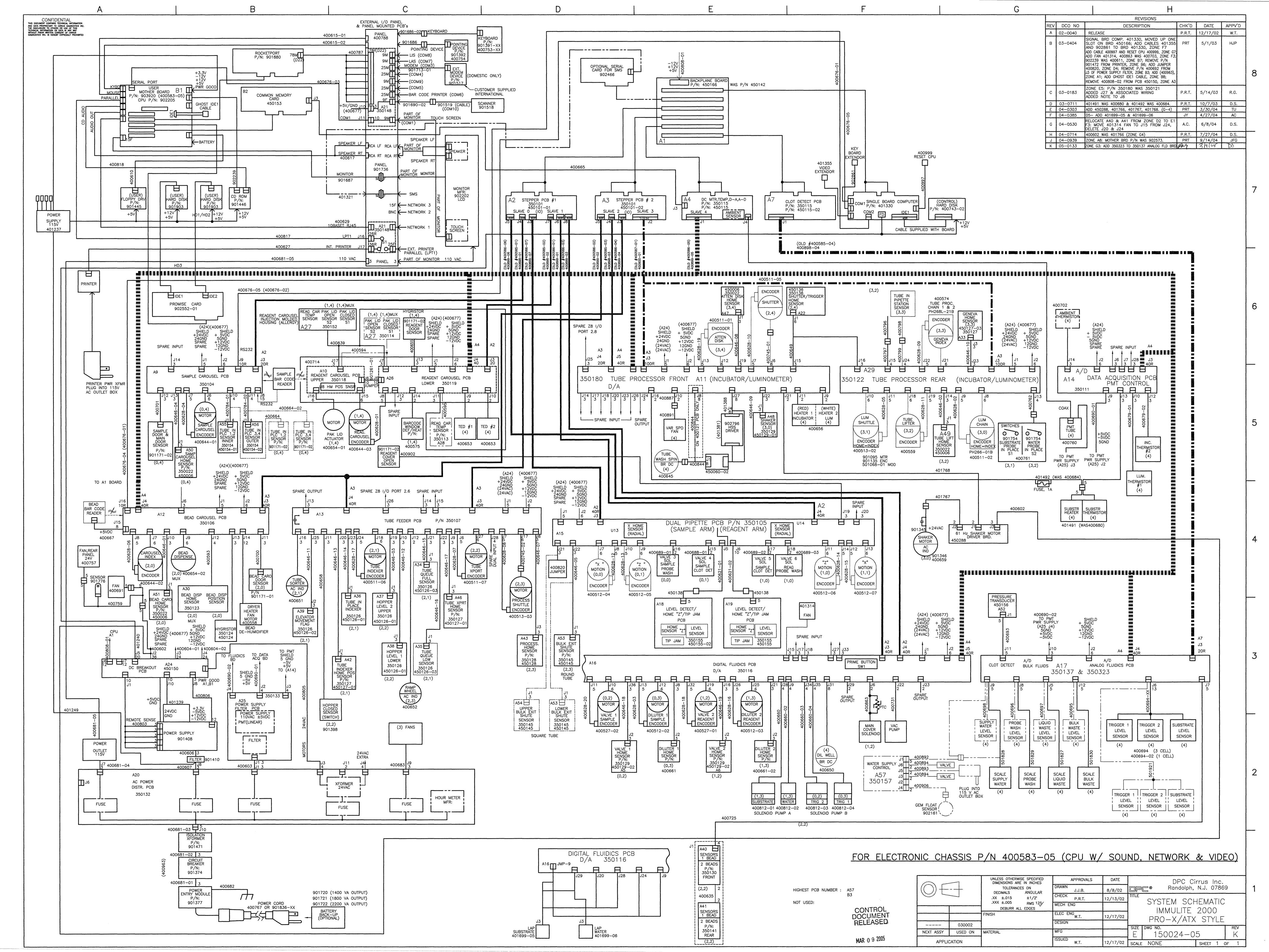
Chapter 13: Fluidics, Chassis and Isometric Drawings

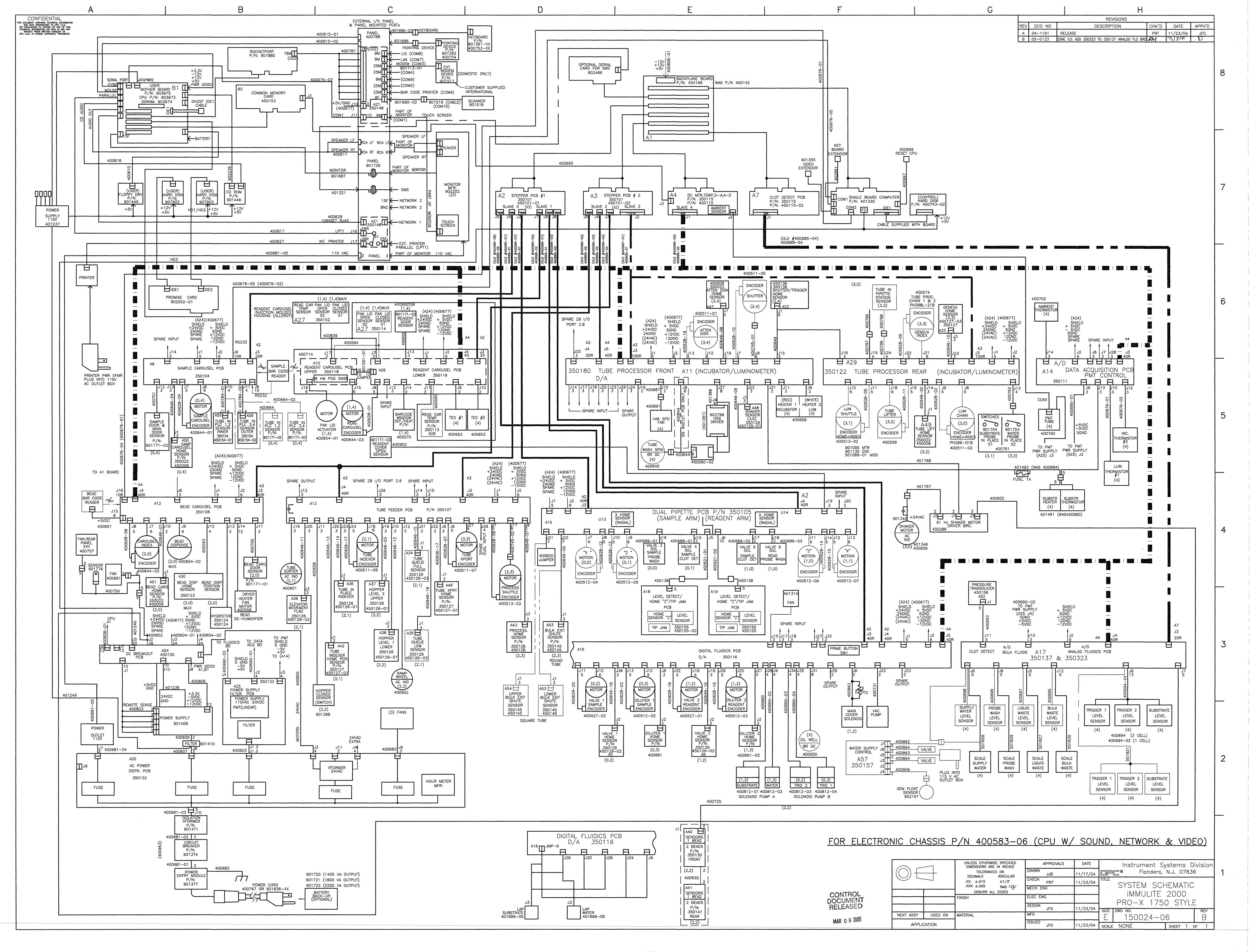
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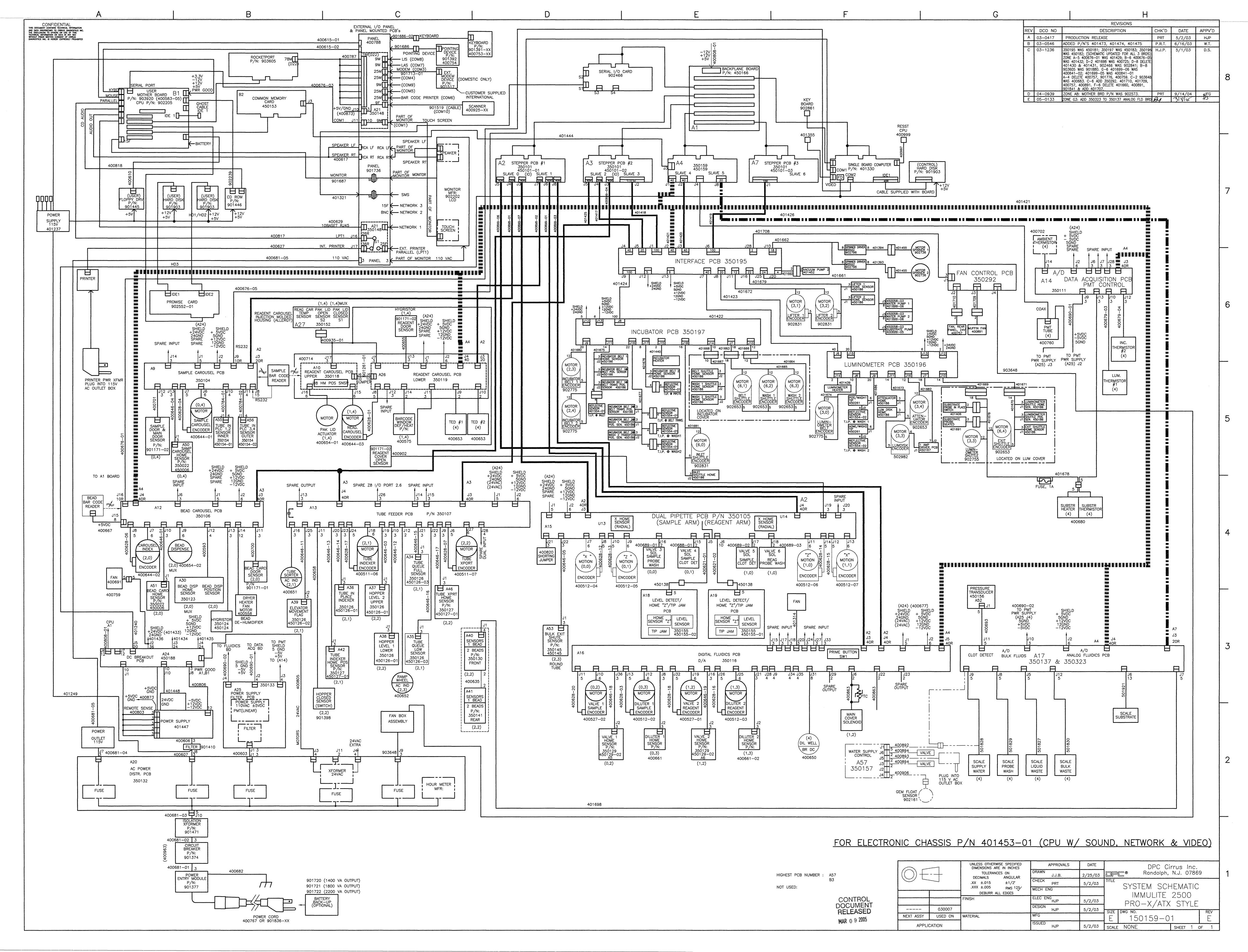


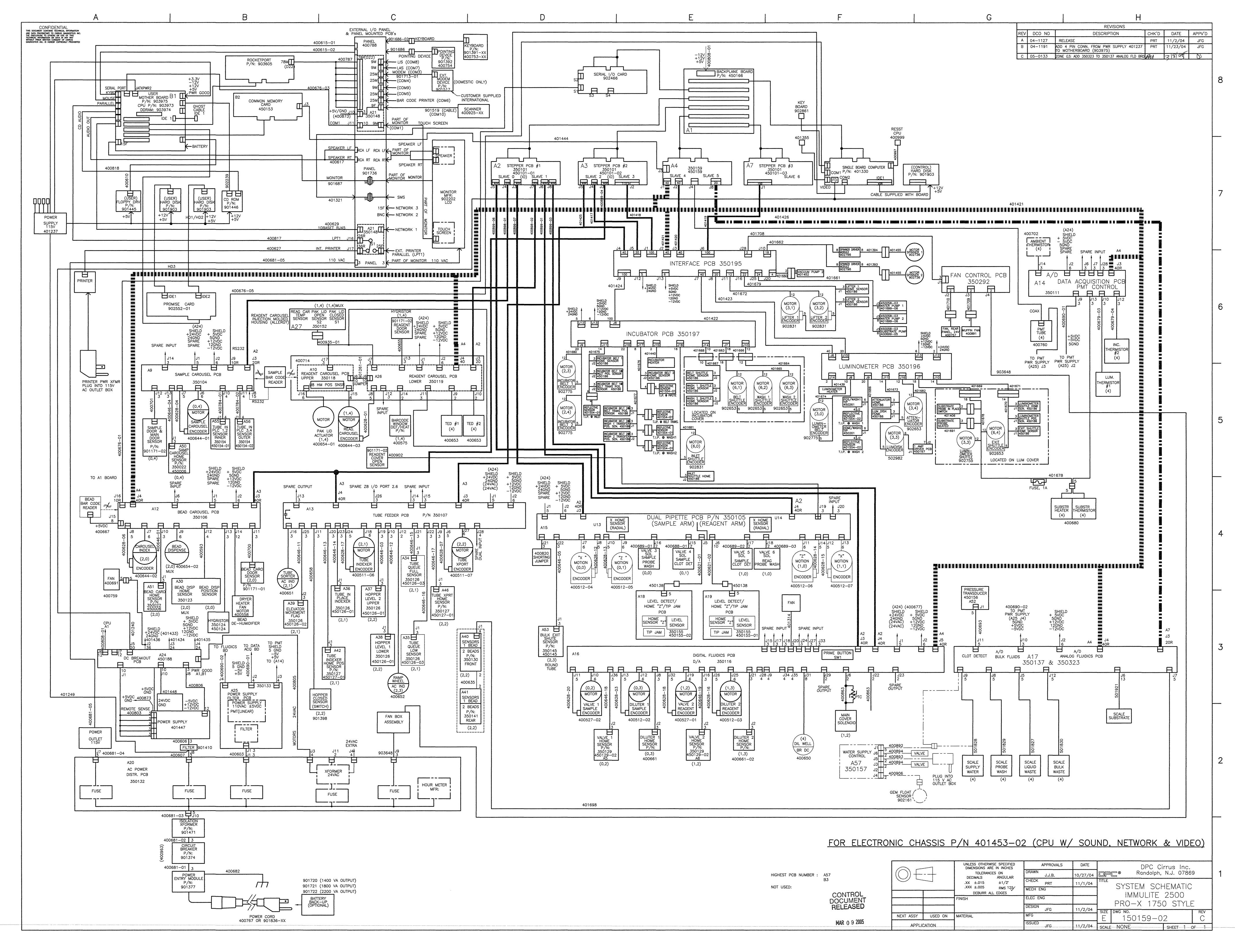


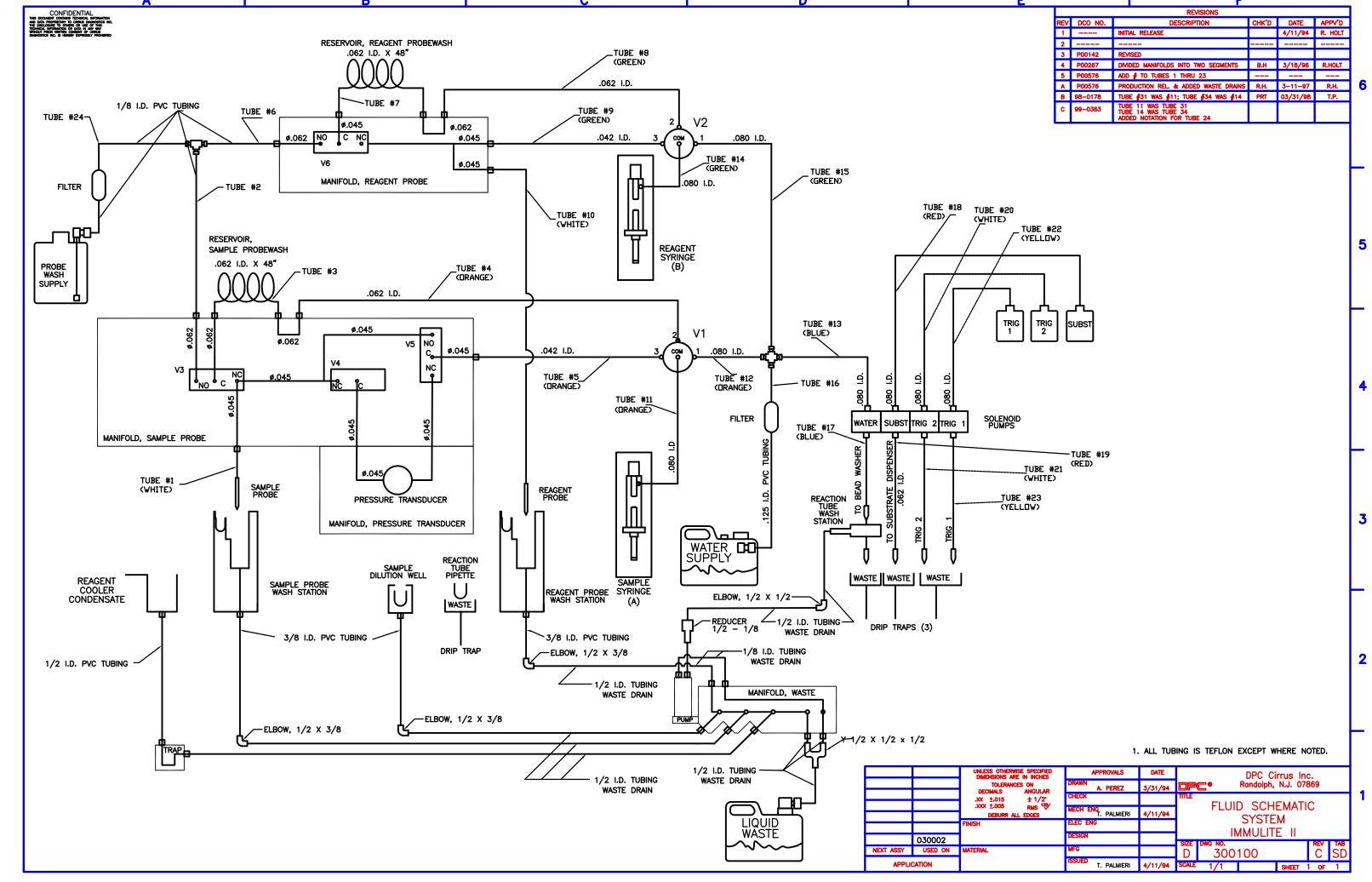


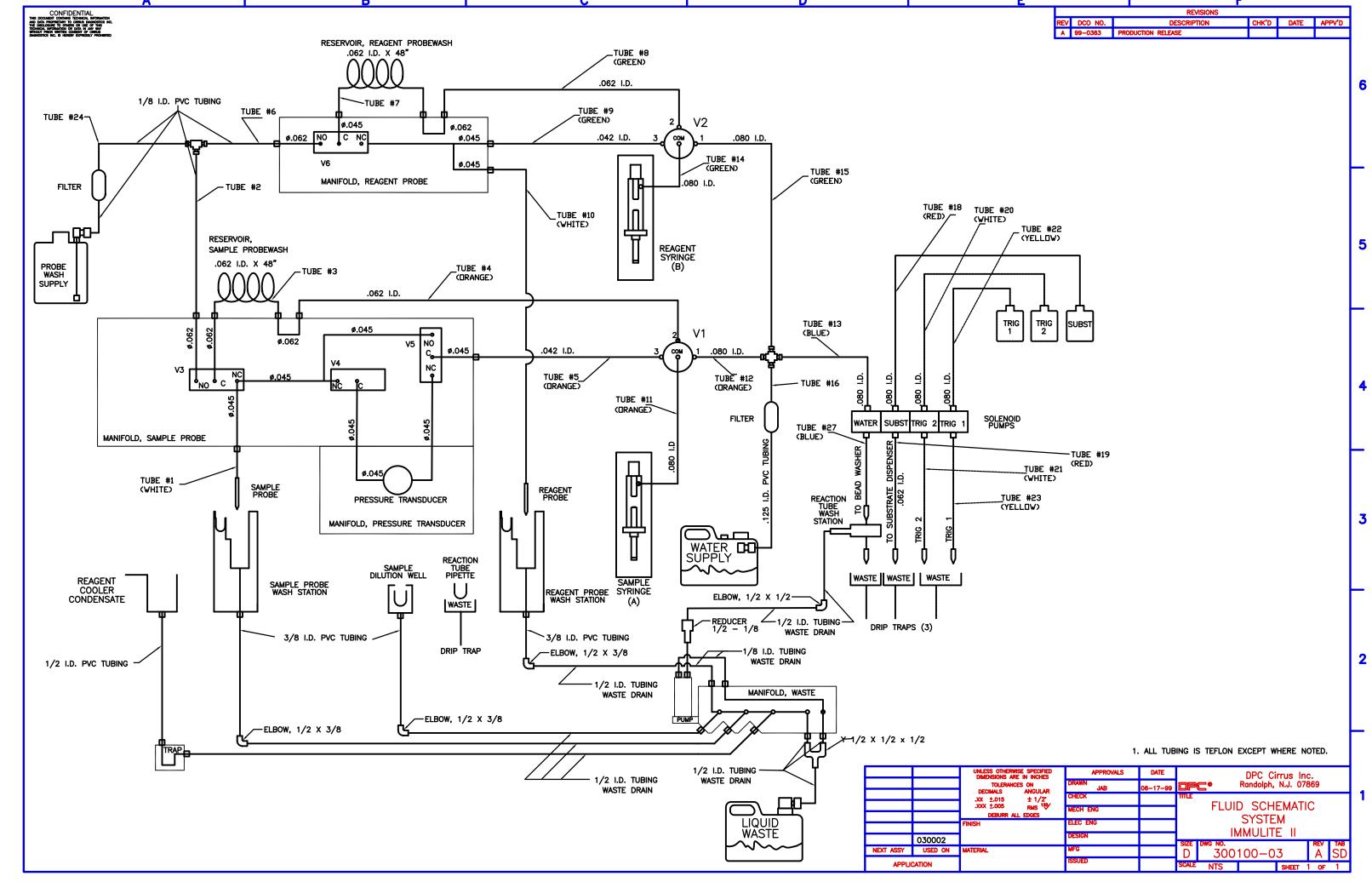


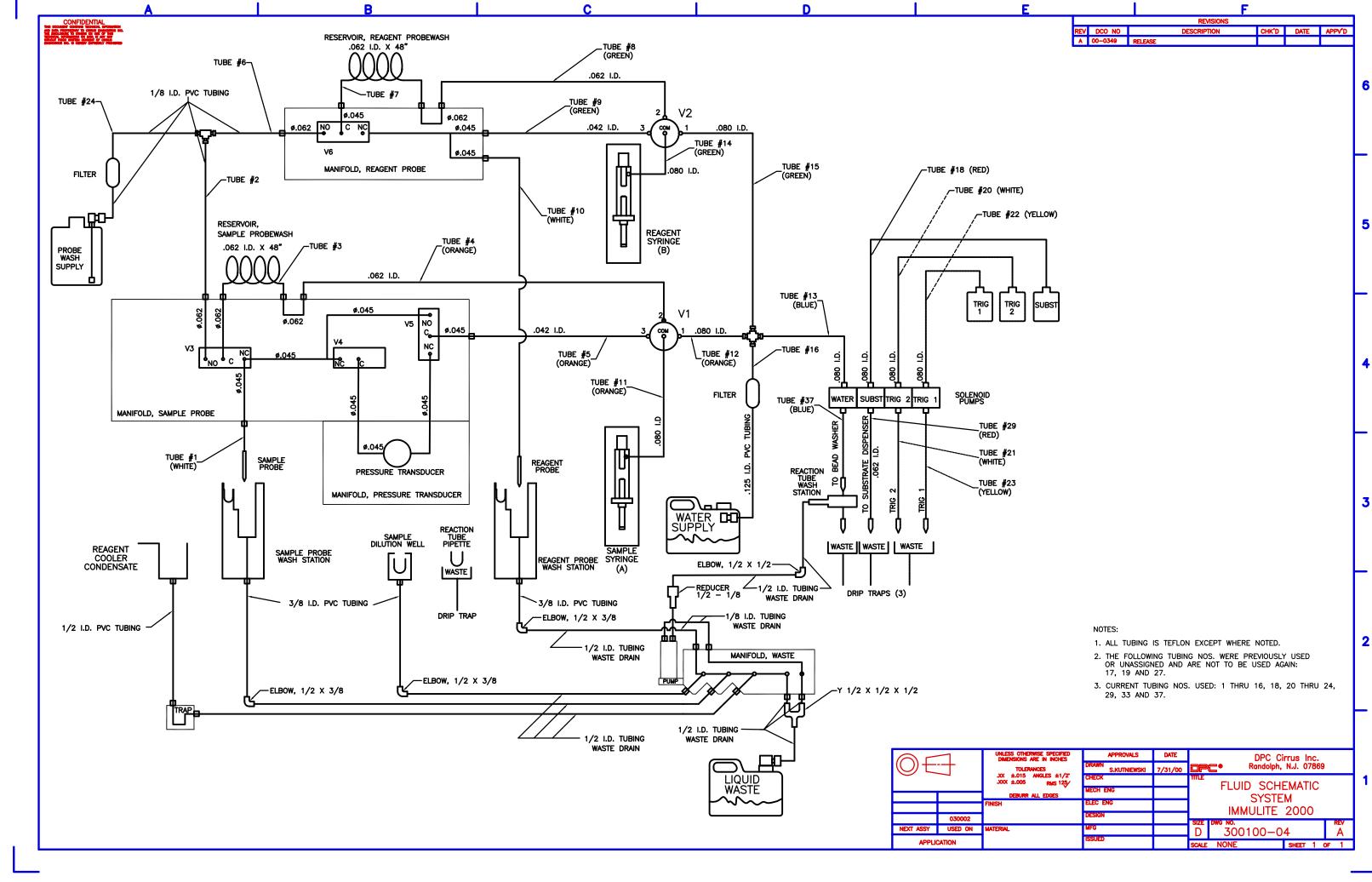


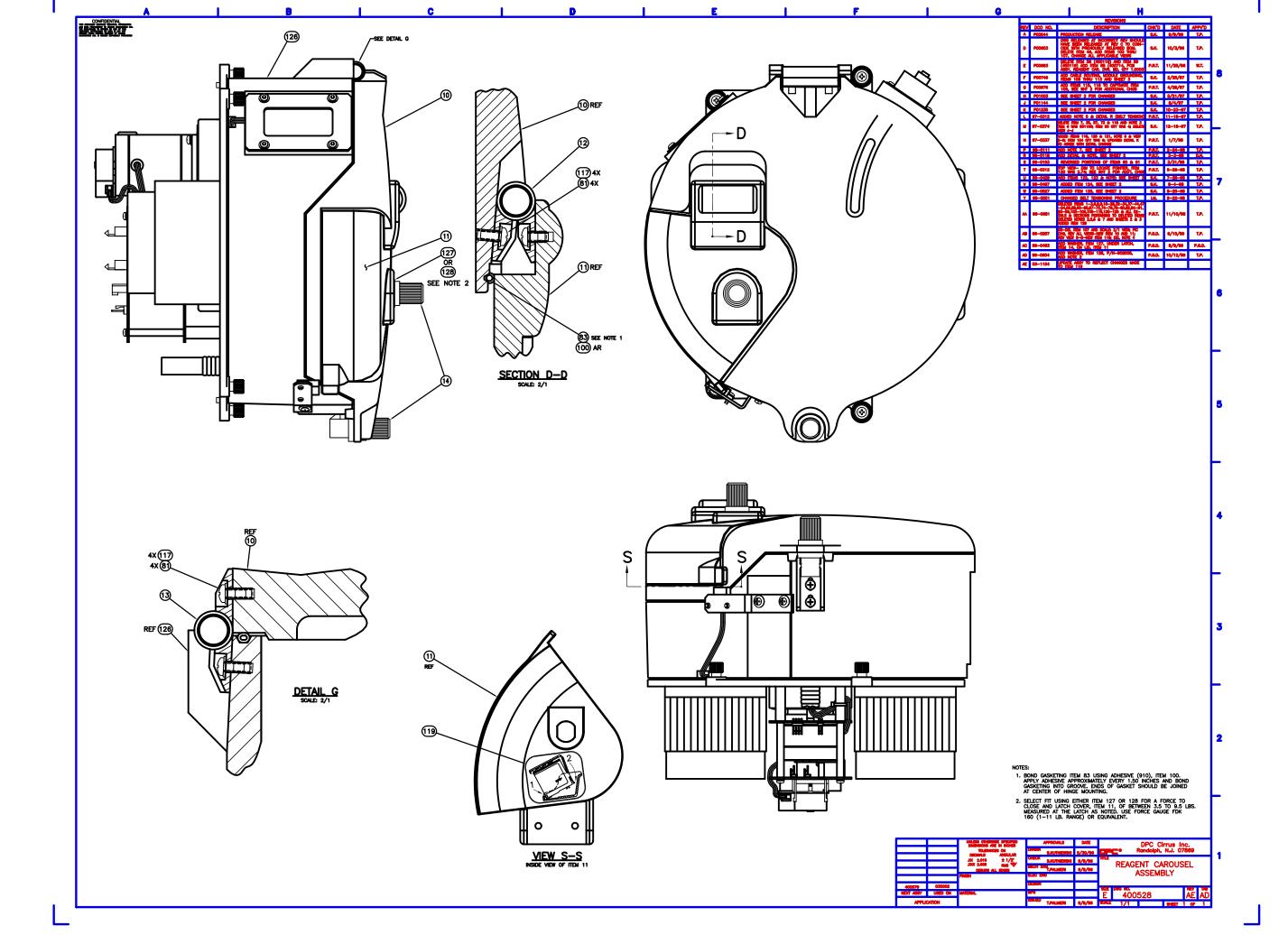


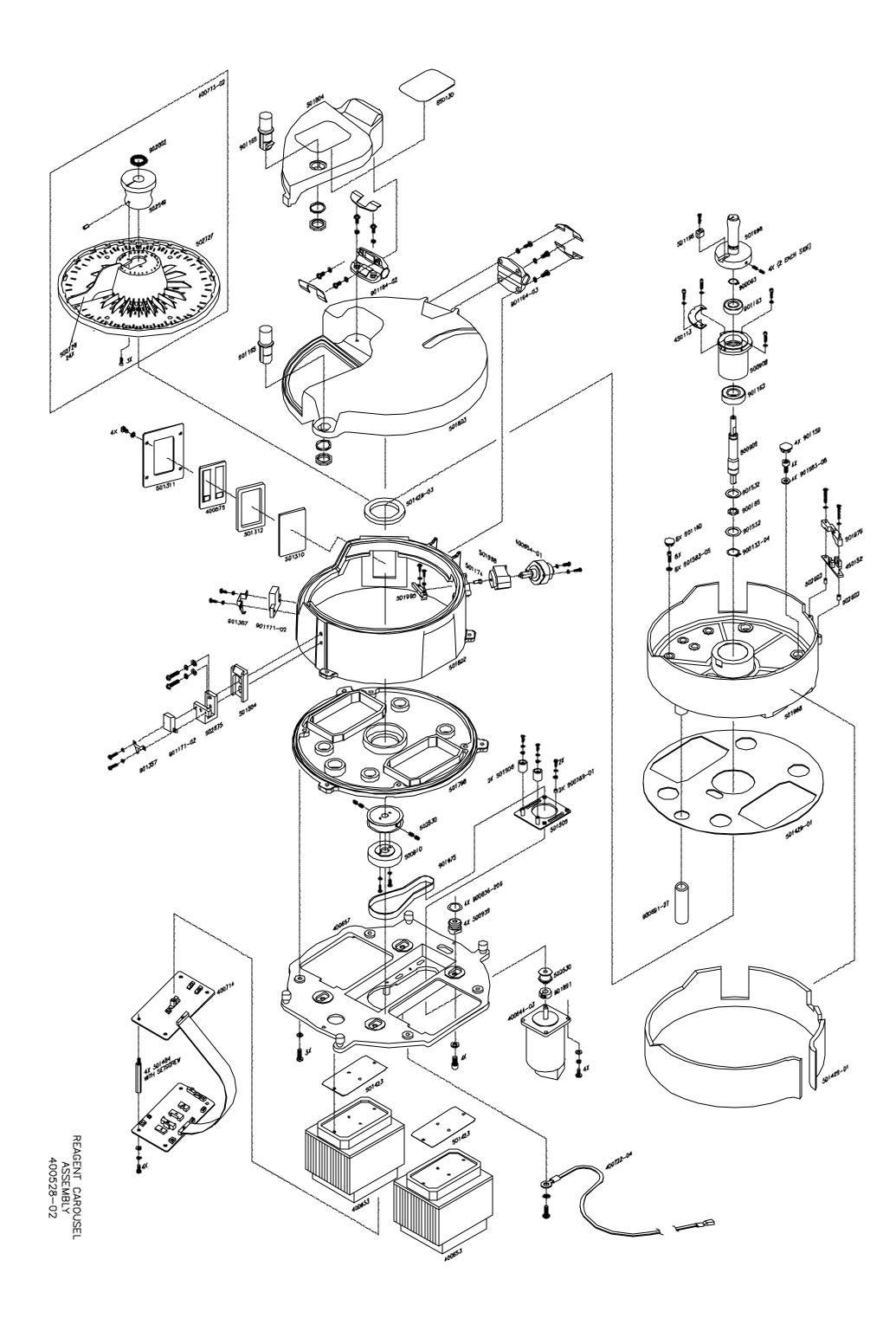


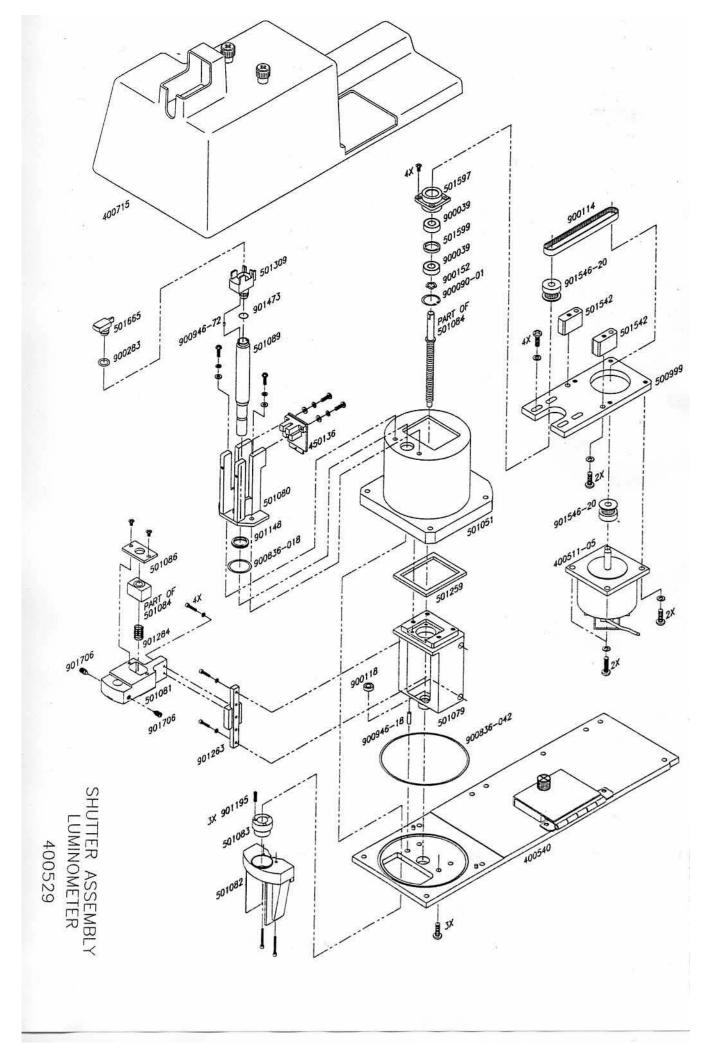


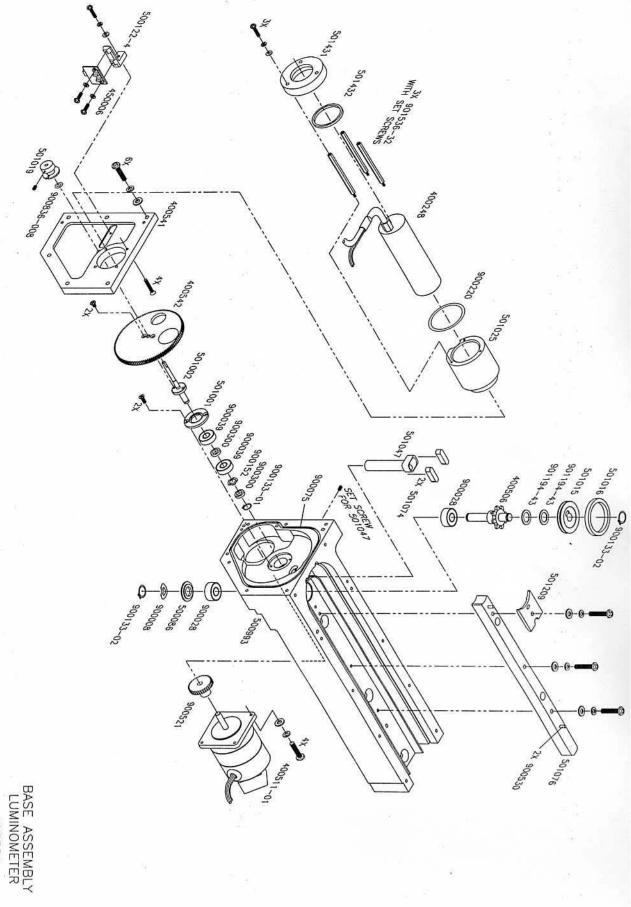


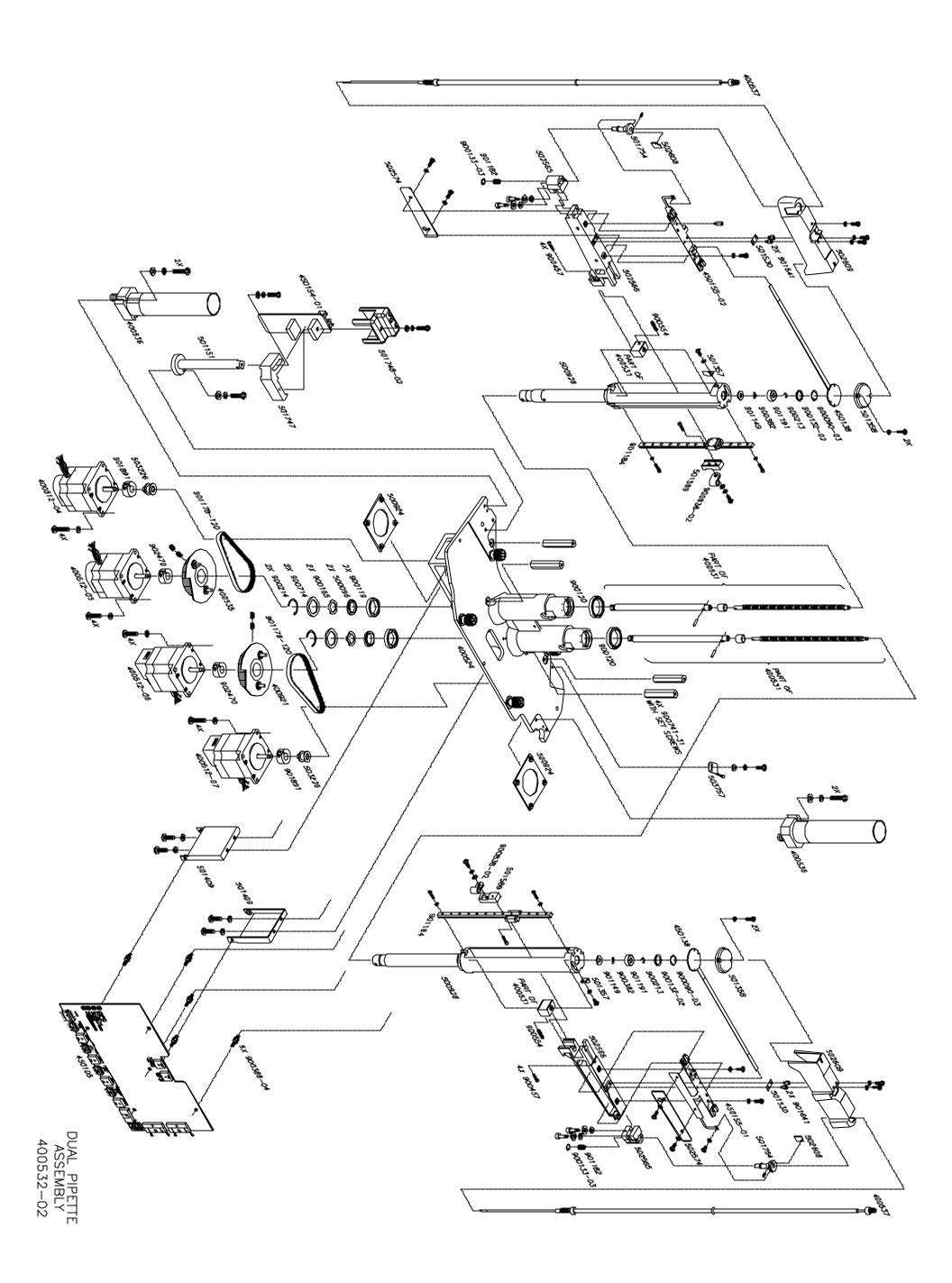


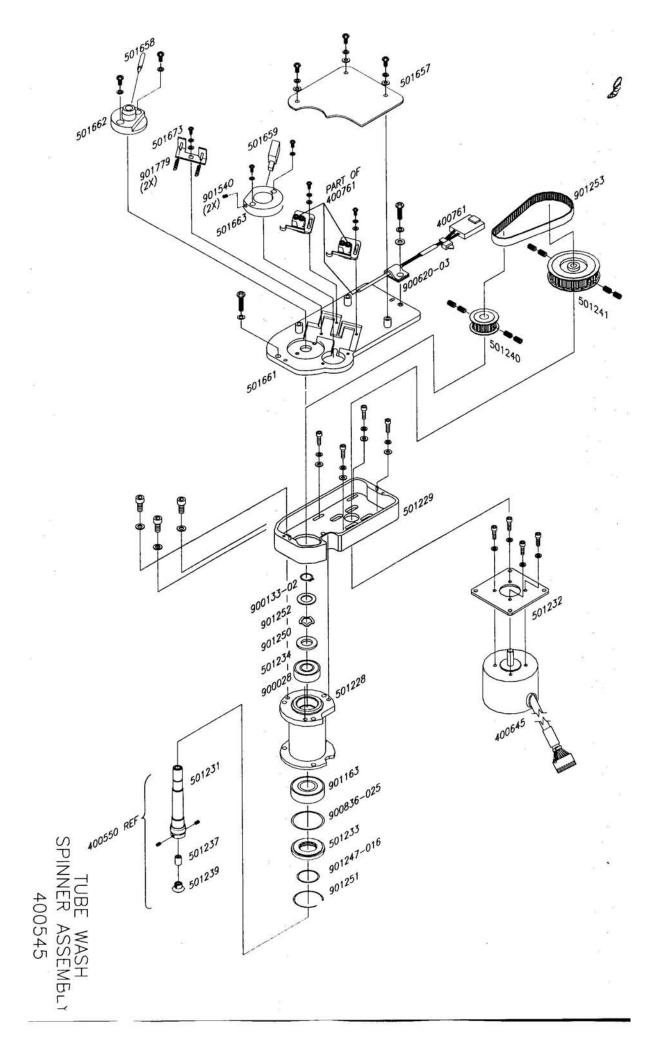


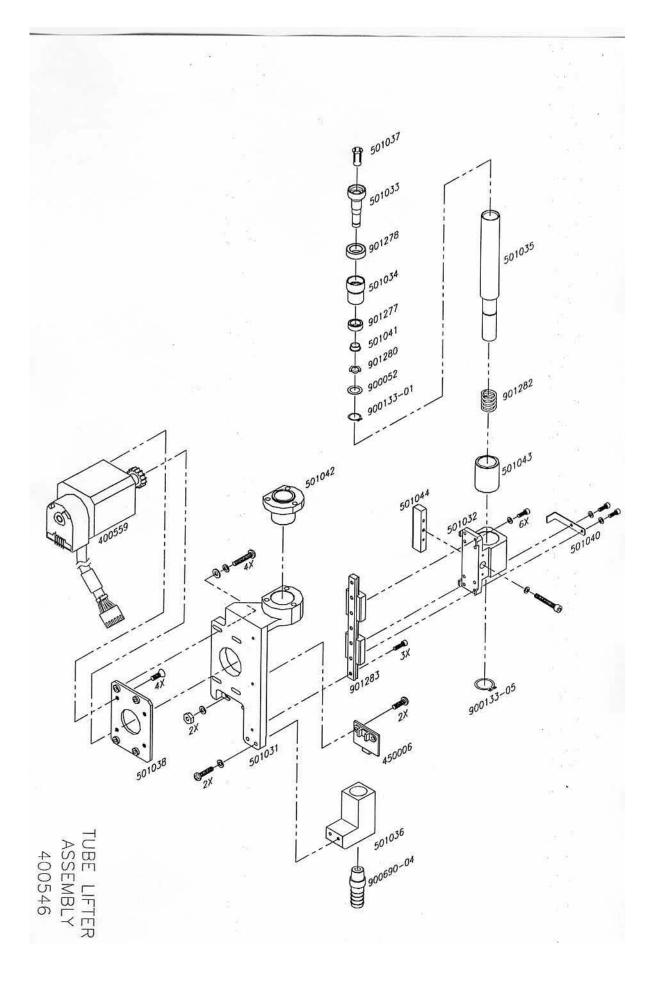


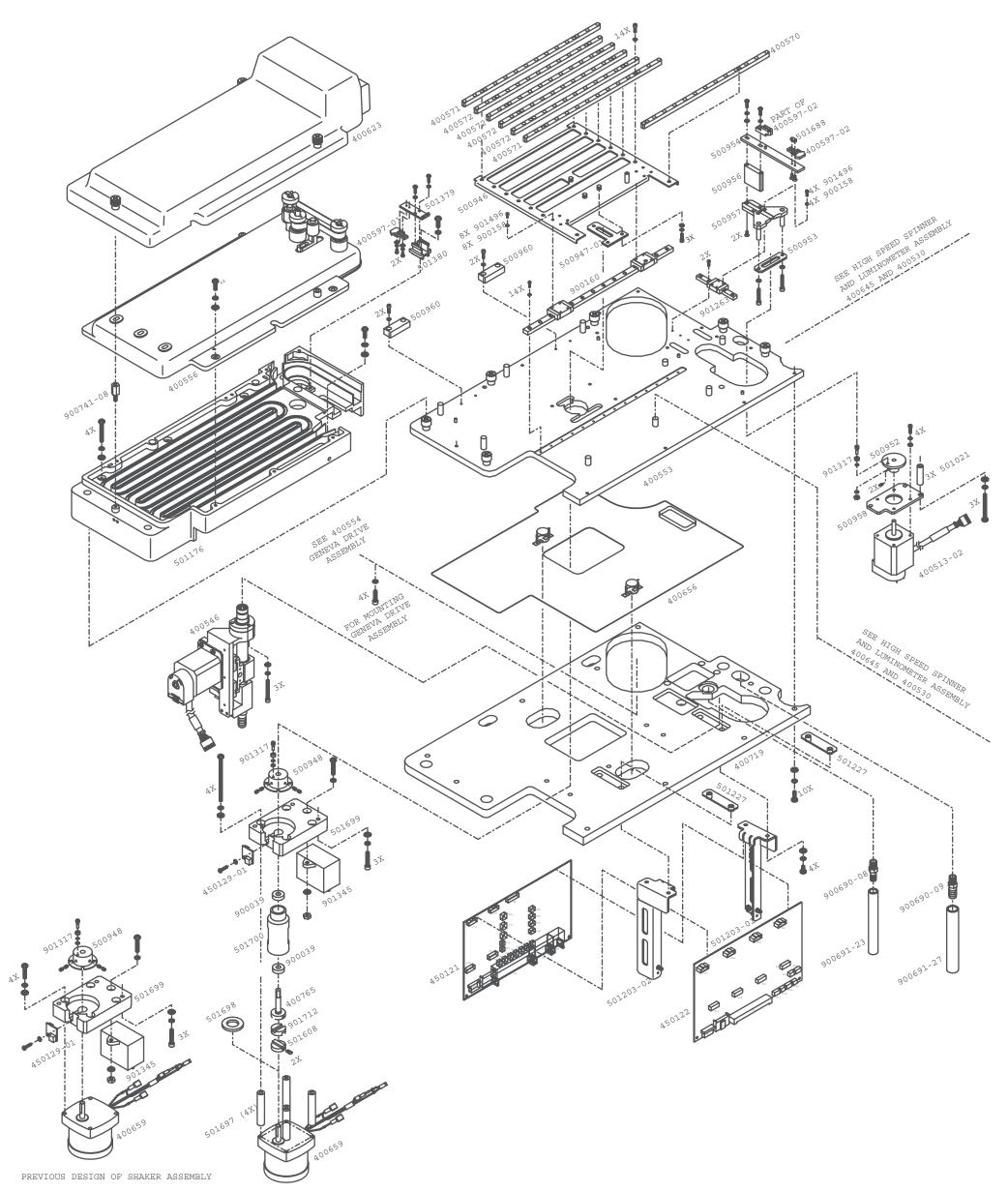




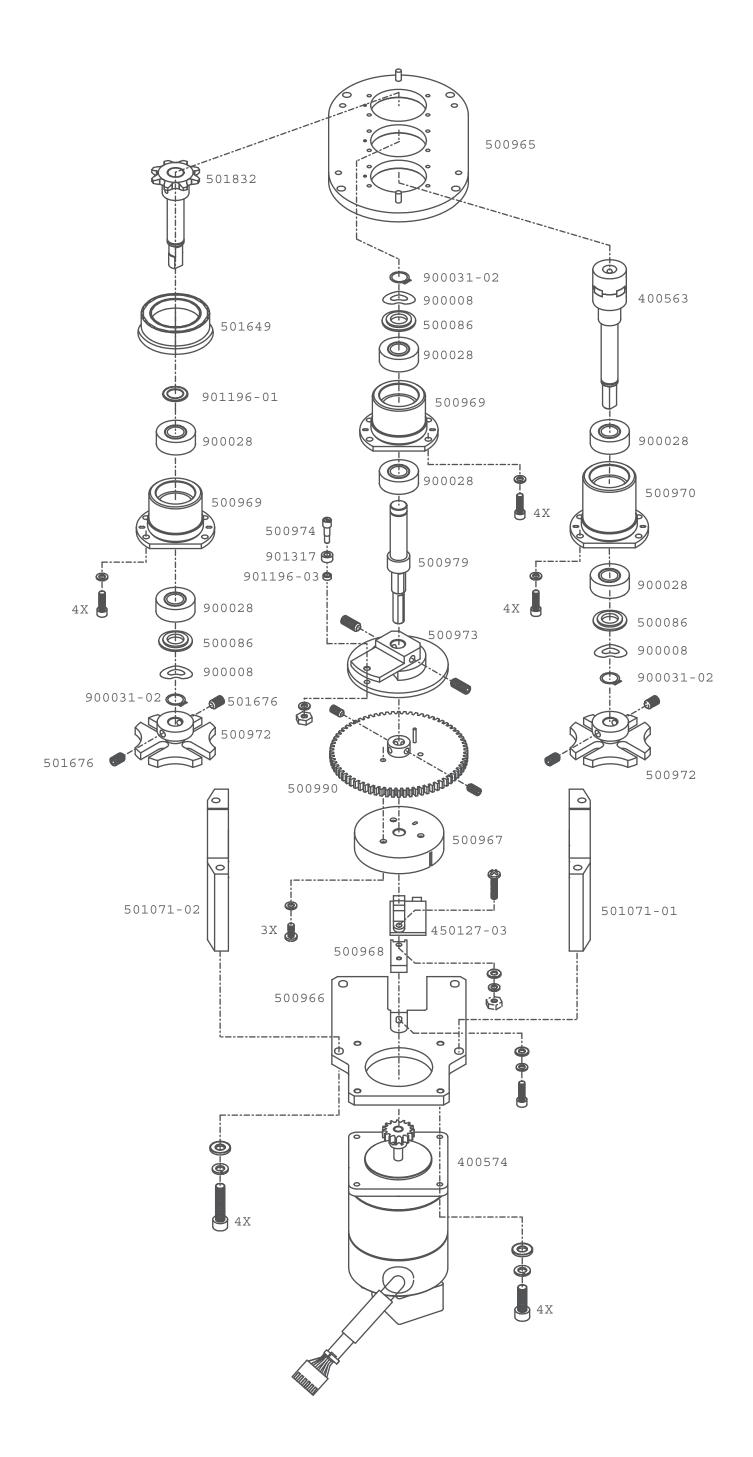


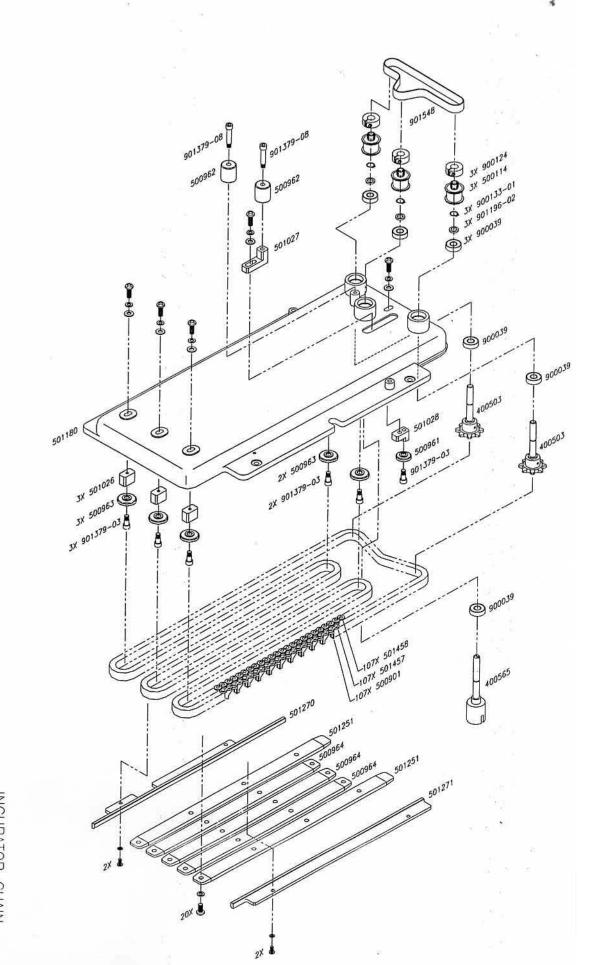




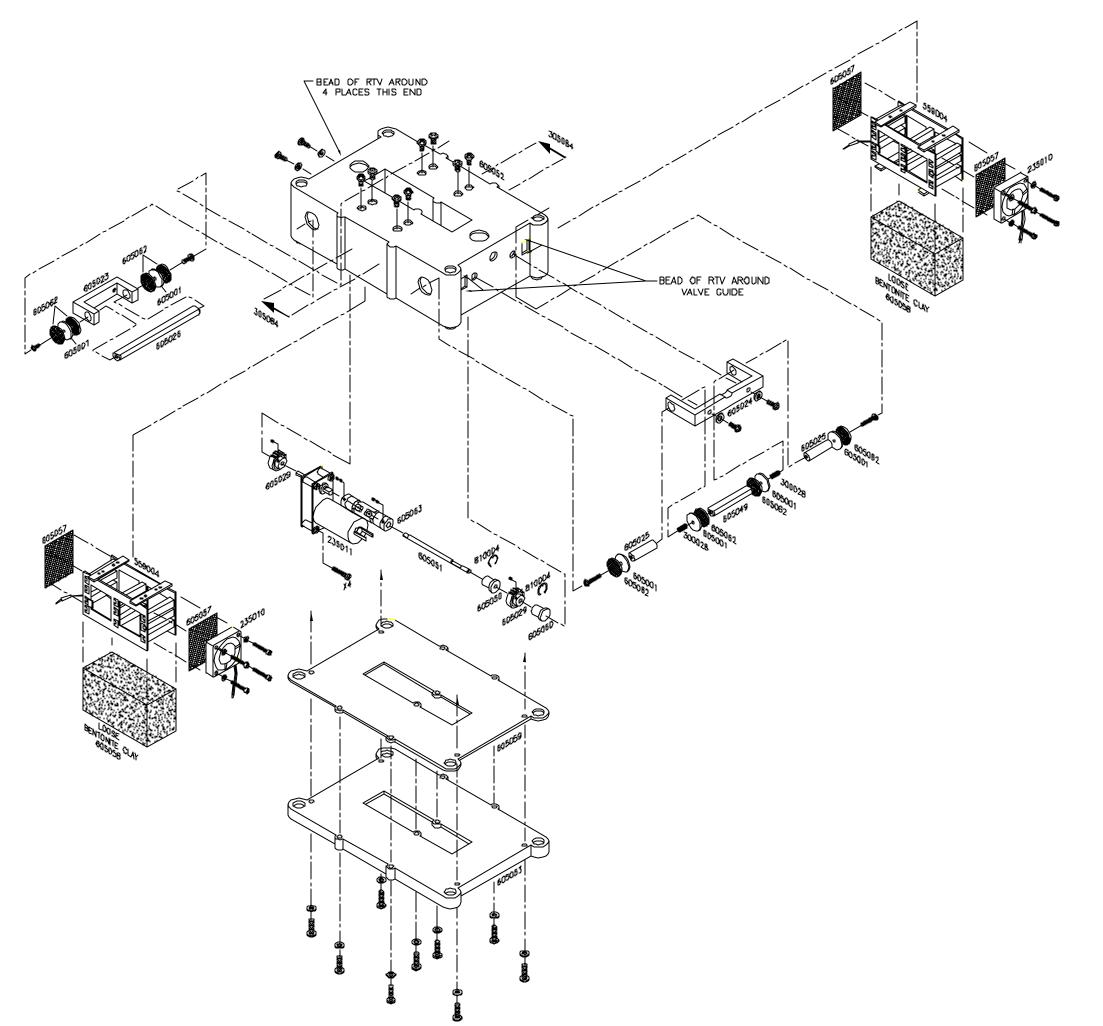


NEW DESIGN OF SHAKER ASSEMBLY



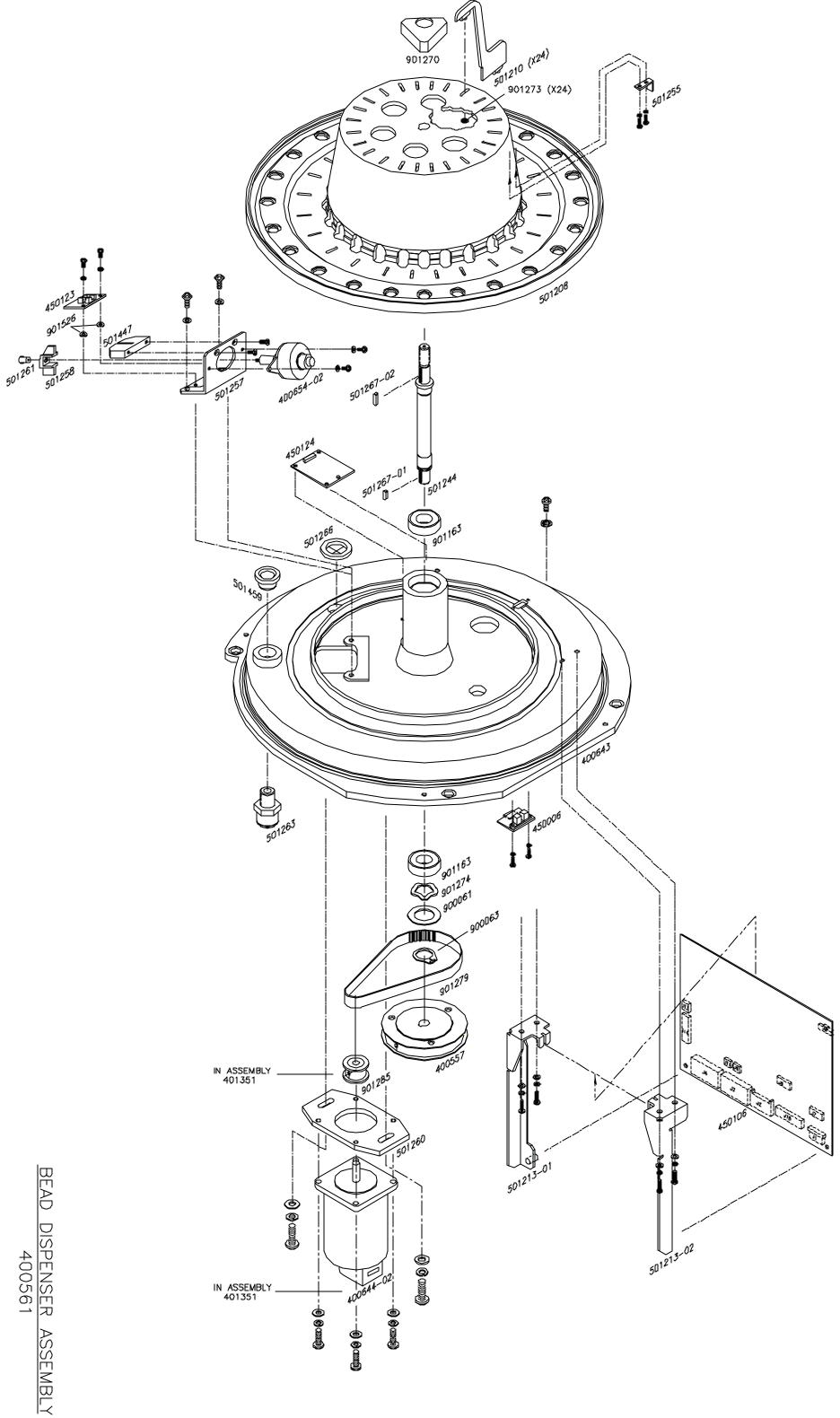


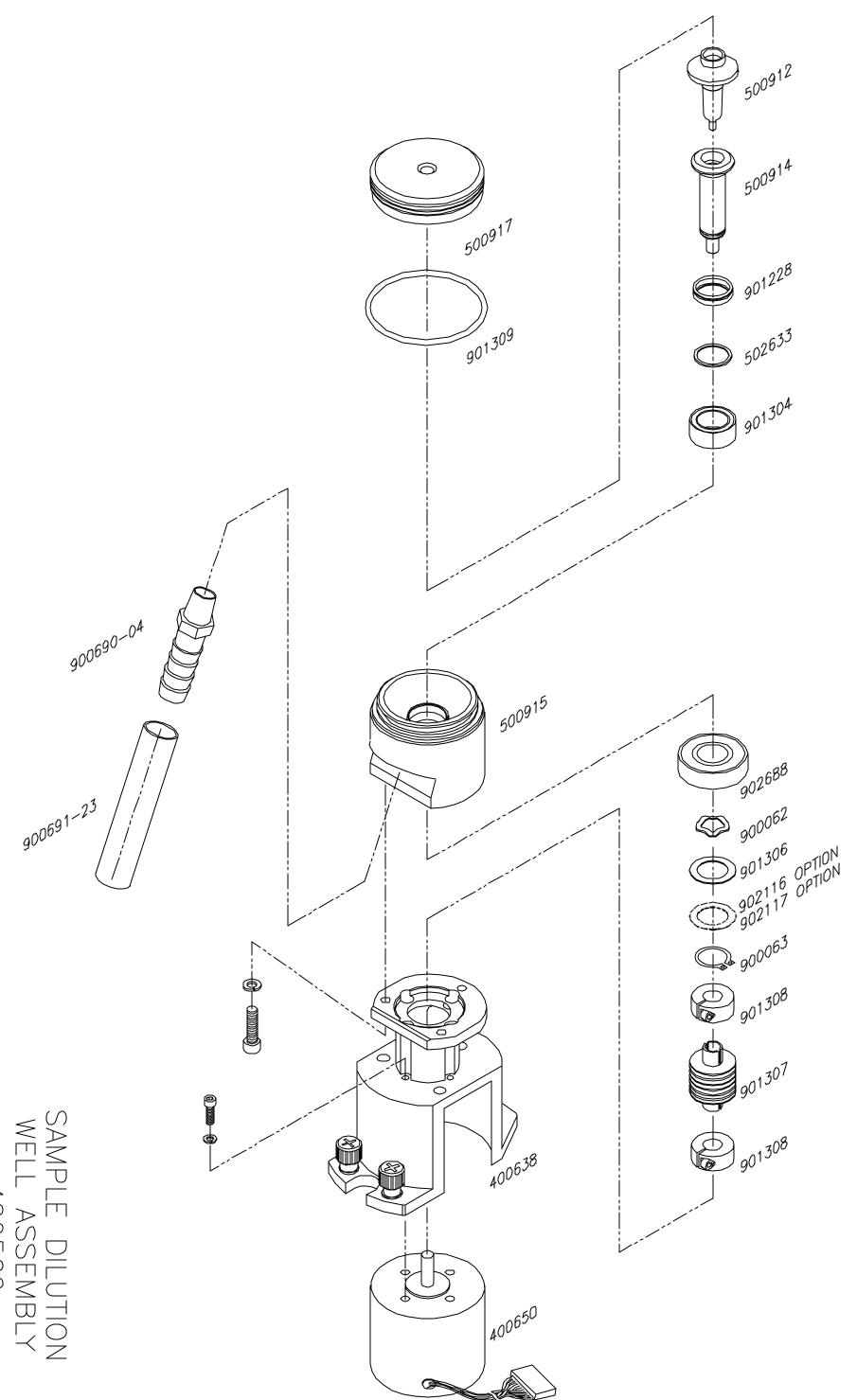
INCUBATOR CHAIN ASSEMBLY 400556



NOTE: ALL PART NUMBERS EXCEPT FOR ASSEMBLY NUMBER ARE EURO DPC NUMBERS.

<u>DEHUMIDIFIER ASSEMBLY</u> 400558





SAMPLE DILUTION WELL ASSEMBLY 400562

Assembly 400577		· ·					
	Component	Rev	Item	Component Description	Qty Per Assy	U/M	
	400609	A	001	ALIGNMENT BAR ASSEMBLY	1.00	EA	
	450301-03	C	002	PCB ASSY, TUBE FEEDER MODULATED SENSOR	2.00	EA	
	450301-02	C	003	PCB ASSY, TUBE FEEDER MODULATED SENSOR	1.00	EA	
	501094	D	004	SHAFT, 3.00, TUBE FEEDER	1.00	EA	
	501095	A	005	SHAFT, 2.31, TUBE FEEDER	1.00	EA	
	501099	Α	006	BEARING, BELT TENSION, ELEVATOR, TUBE FEEDER	1.00	EA	
	501100	Α	007	SHAFT, ELEVATOR BELT TENSIONER, TUBE FEEDER	1.00	EA	
÷	501101	F	008	SUPPORT, TUBE FEEDER, LEFT HAND	1.00	EA	
	501102	G	009	SUPPORT, TUBE FEEDER, RIGHT HAND	1.00	EA	
	501104	A	010	SUPPORT, BELT, TUBE FEEDER	1.00	EA	
	501132	G	011	BELT, ELEVATOR	1.00	EA	
	501134	В	012	ROD, CONNECTING, TUBE FEEDER	1.00	EA	
	501138	C	014	SPRING GUIDE TUBE FEEDER	1.00	EA	
	501143-01	E	015	GUIDE, TUBE, LEFT, TUBE FEEDER	1.00	EA	
	501143-02	E	016	GUIDE, TUBE, RIGHT, TUBE FEEDER	1.00	EA	
	501144	Α	017	PLATE, AGITATOR, TUBE FEEDER	1.00	EA	
	501146	E	018	HOPPER, ELEVATOR, TUBE FEEDER	1.00	EA	
	501277	Α	019	BAR, SUPPORT, ELEVATOR, TUBE FEEDER	1.00	EA	
	501375	D	020	PULLEY, ELEVATOR, TUBE FEEDER	2.00	EA	
	501386	В	021	PULLEY, DRIVE, ELEVATOR BELT	1.00	EA	
	900063	D	022	RING, RETAINING, EXTERNAL, 1/2 SHAFT	1.00	EA	
	900061	Α	023	WASHER, THRUST, $1/2$ ID X $15/16$ OD X 0.062 THK, S.S.	1.00	EA	
	900133-01	J	024	RING, RETAINING, EXTERNAL, 1/4 SHAFT	12.00	EA	
	900152	A 1	025	SPRING, BEARING PRELOAD, S.S., 0.265 ID X 0.367 OD	4.00	E A	
	H0601183203		026	SCREW, SET, CUP POINT HEX SOCKET, 8-32 X 3/16, SS	10.00	EA	
	H2051163200	-	027	NUT, HEX CAP (ACORN), 6-32, SS	6.00	EA	
	900019	Α	028	SPACER, SHAFT, 1/4 ID X 3/8 OD X 0.031 THK, S.S.	6.00	EA	
	400651	C	029	CABLE ASSEMBLY, AC MOTOR/SWITCH TUBE SORTER	1.00	EA	

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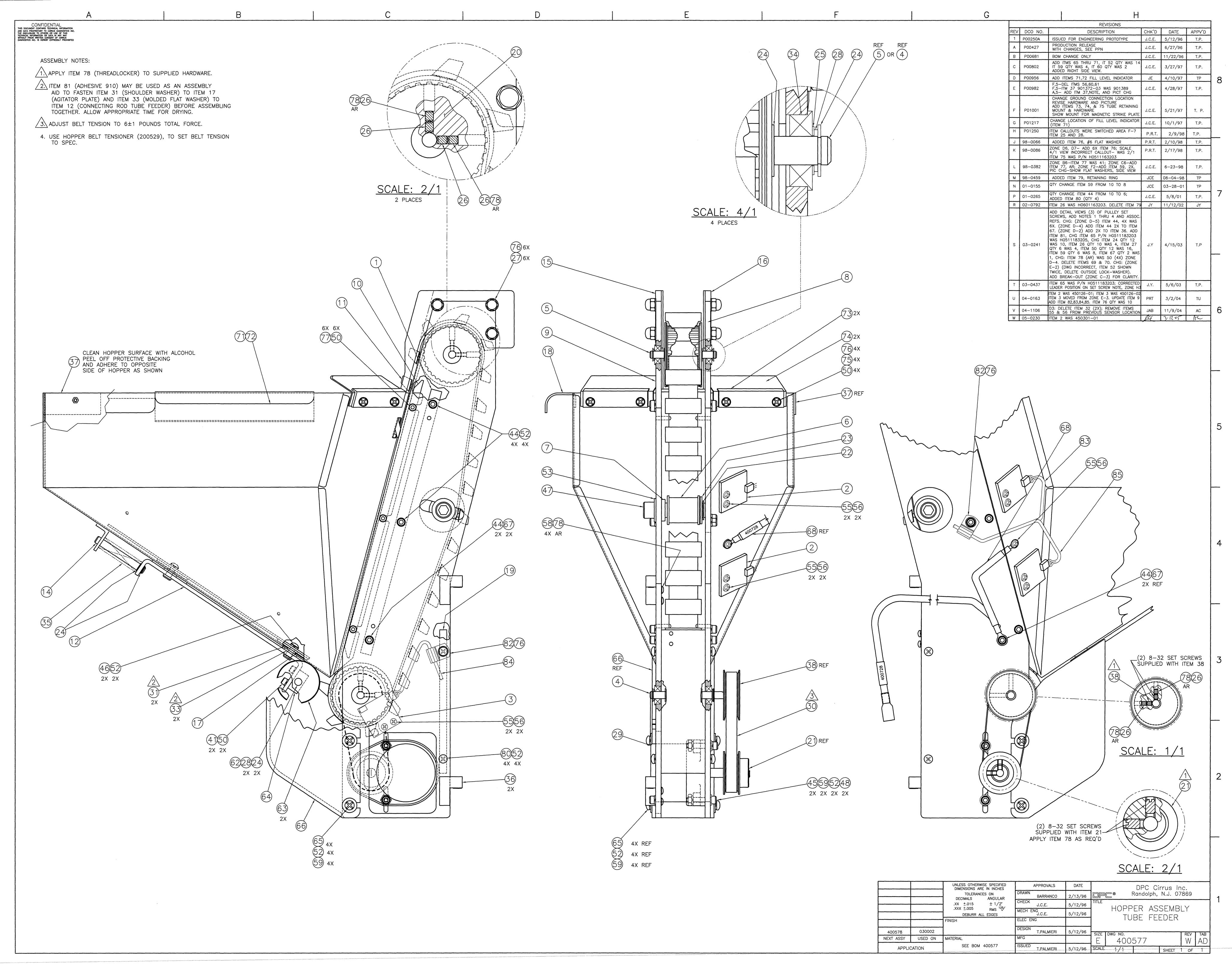
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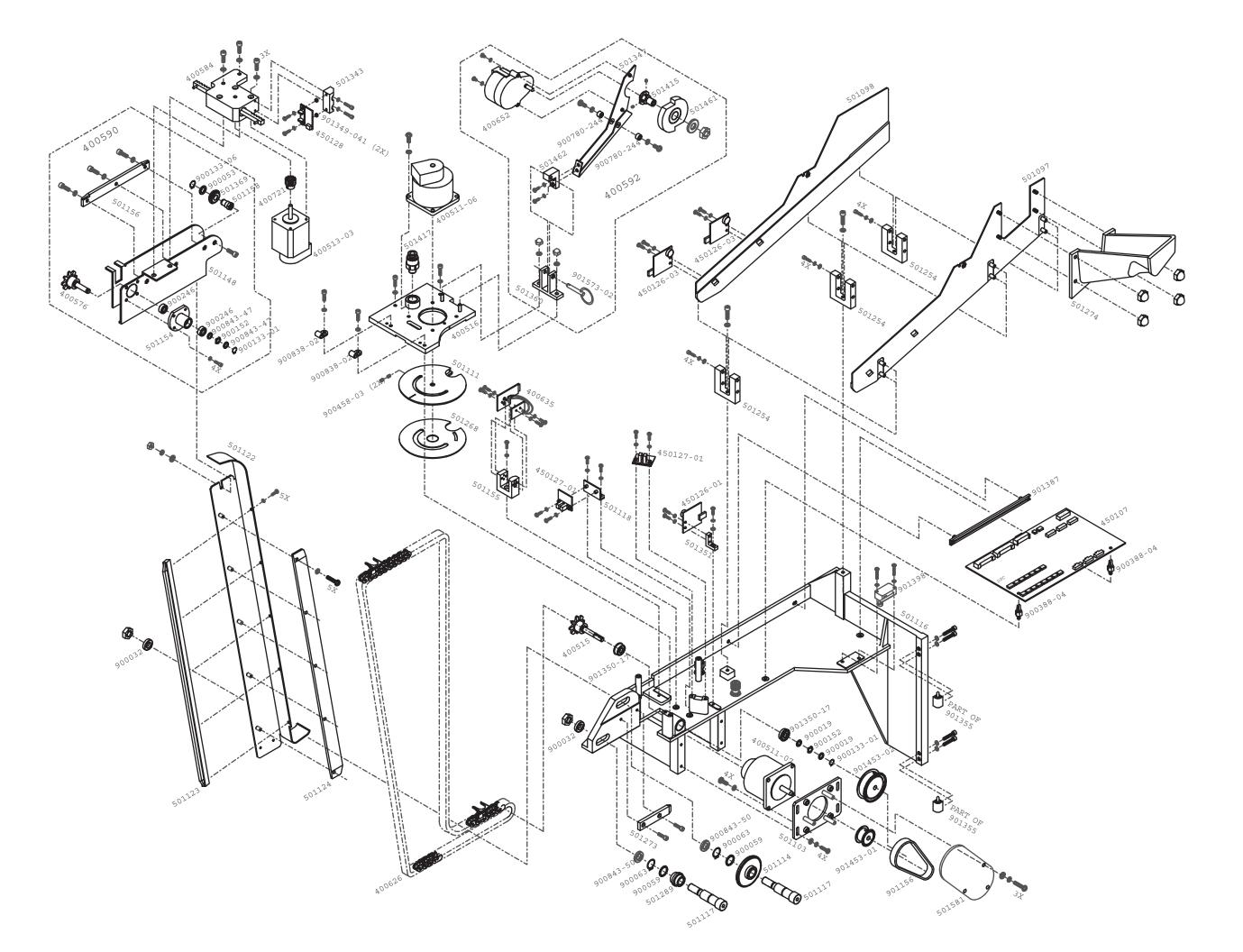
Assembly 400577		· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·			
	Component	Rev	Item	Component Description	Qty Per Assy	U/M	
	901572	A	030	BELT, TIMING, 1/5 PITCH, 3/8 WIDE, 49 GROOVE	1.00	EA	
	501455	A	031	WASHER, SHOULDER	2.00	EA	
	901349-102	C	033	WASHER, FLAT, MOLDED	2.00	EA	
	901350-17	D	034	BEARING, RDL, FLG, .2500 ID X .6250 OD X .1960 W, SHLD	4.00	EA	
	901698	Α	035	SPRING, COMPRESSION, .035 WD X .480 OD X 2.0 FL, S.S.	1.00	EA	
	901355	Α	036	HINGE, LIFT-OFF, OFFSET MINI	2.00	EA	
	901372-03	\mathbf{c}	037	STRIKE, STEEL, ADHESIVE MOUNT	1.00	EA	
	901453-02	Α	038	PULLEY, TIMING BELT, 1/5 PITCH, 7/16 W, 24 GROOVES	1.00	EA	
	Н0591163208		041	SCREW, CAP, HEX SOCKET, 6-32 X 1/2, SS	2.00	EA	
	Н0591183210		044	SCREW, CAP, HEX SOCKET, 8-32 X 5/8, SS	6.00	EA	
	Н0591183114		045	SCREW, CAP, HEX SOCKET, 8-32 X 7/8, SS	2.00	EA	
	Н0641183208	-	046	SCREW, BUTTON HD HEX SOCKET, 8-32 X 1/2, SS	2.00	EA	
	Н0591131614	-	047	SCREW, CAP, HEX SOCKET, 3/8-16 X 7/8, SS	1.00	EA	
	H2001183200		048	NUT, HEX, 8-32, SS	2.00	EA	
	Н3011100600		050	WASHER, SPLIT LOCK, #6, SS	12.00	EA	
	Н3011100800		052	WASHER, SPLIT LOCK, #8, SS	16.00	EA	
	Н3001103800	-	053	WASHER, FLAT, 3/8, SS	1.00	EA	
	H0511144006		055	SCREW, PAN HD CROSSED RECESSED, 4-40 X 3/8, SS	7.00	EA	
	Н3011100400		056	WASHER, SPLIT LOCK, #4, SS	7.00	EA	
	Н0511163207		058	SCREW, PAN HD CROSSED RECESSED, 6-32 X 7/16, SS	4.00	EA	
	H3001100800		059	WASHER, FLAT, #8, SS	6.00	EA	
	501442	Α	062	ROLLER, SHAFT AGITATOR	1.00	EA	
	501443	Cl	063	ROLLER, HOPPER AGITATOR	2.00	EA	
	501444	В	064	MOUNT, AGITATOR SHAFT	1.00	EA	
	H0511183206		065	SCREW, PAN HD CROSSED RECESSED, 8-32 X 3/8, SS	4.00	EA	
	501580	C	066	GUARD, HOPPER AGITATOR	1.00	EA	
	H3021100800	-	067	WASHER, INTERNAL TOOTH LOCK, #8, SS	2.00	EA	
	400728	Α	068	CABLE ASSEMBLY, GROUND STRAP, DUAL	1.00	EA	

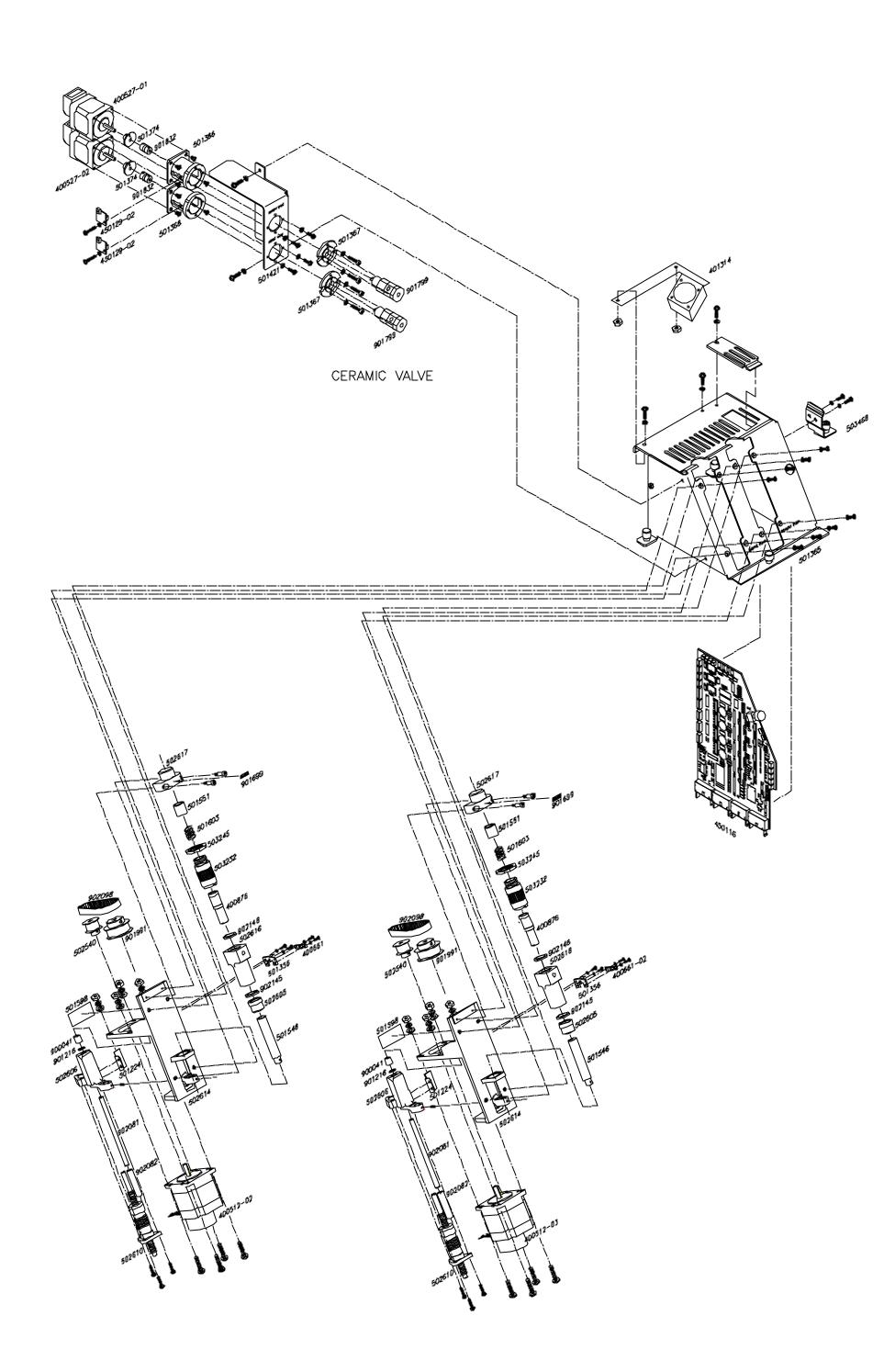
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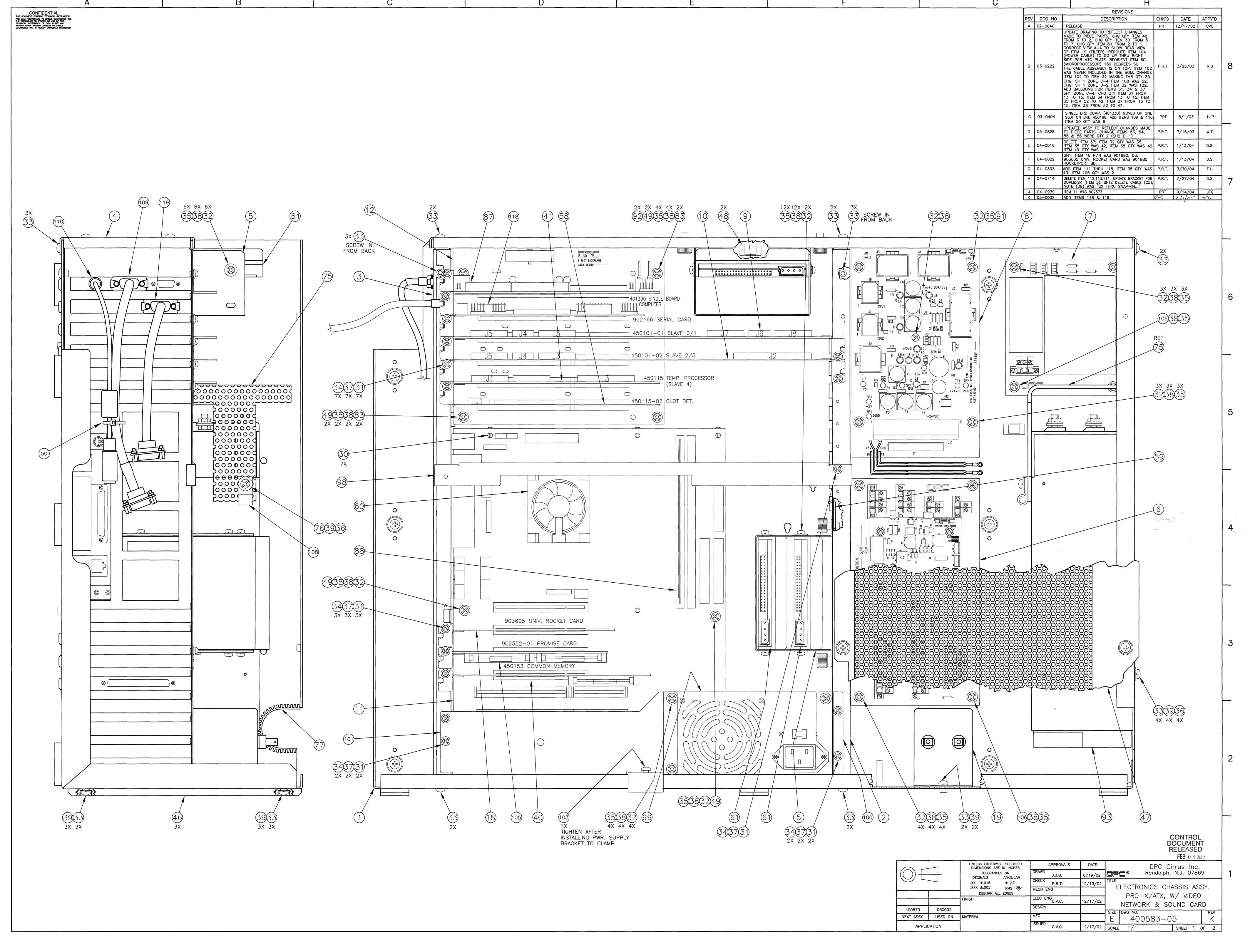
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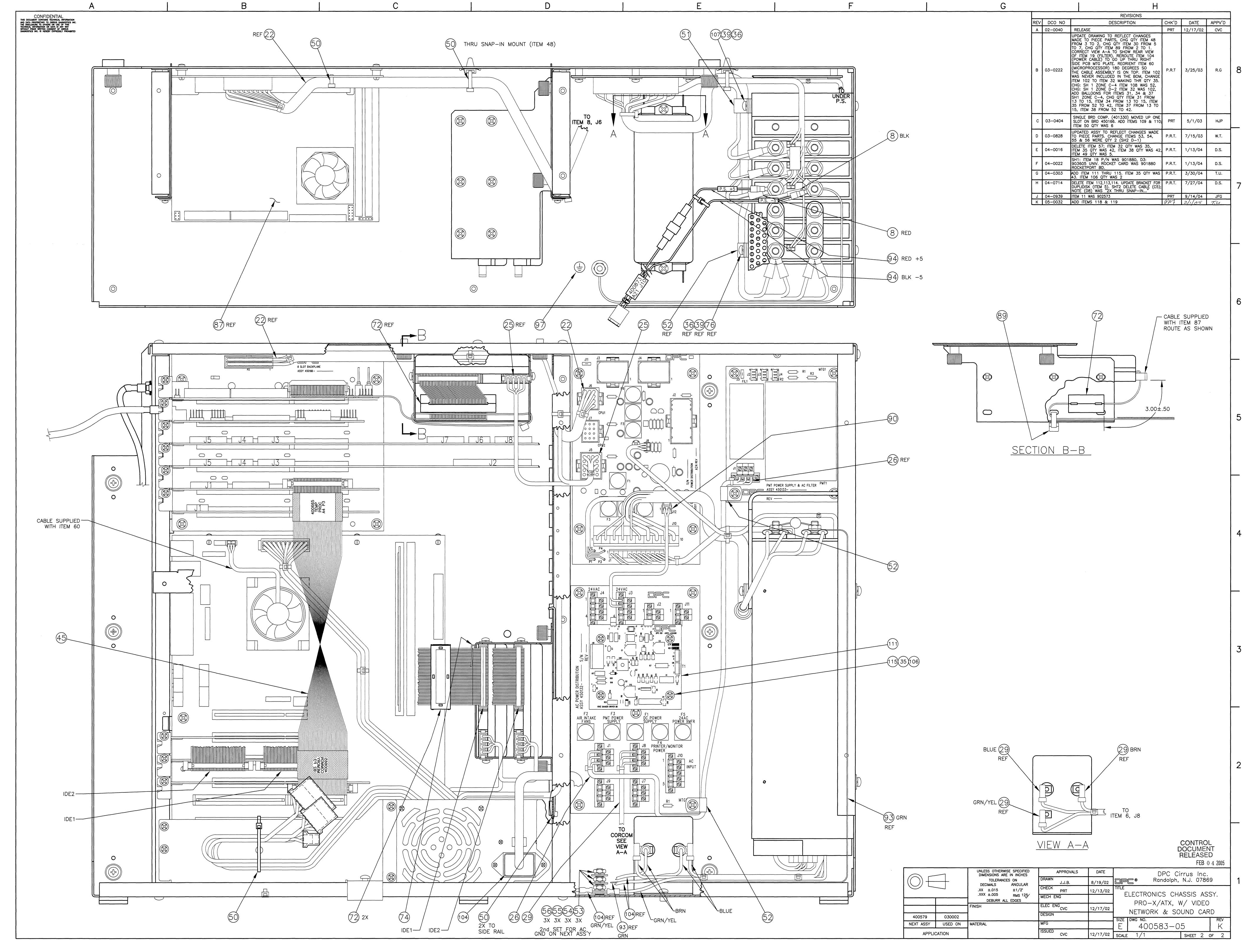
	Assembly 400577	· · · · · · · · · · · · · · · · · · ·					
	Component	Rev	Item	Component Description	Qty Per Assy	U/M	
	501618	В	071	INDICATOR, LEVEL, HOPPER	1.00	EA	
	900779 AS REQUIRED	C	072	ADHESIVE, RTV 732, SILICONE RUBBER, GRAY OR CLEAR	0.00	TB	
	501633	C	073	MOUNT, RETAINING, TUBE HOPPER	2.00	EA	
	501634	D	074	RETAINER, TUBE HOPPER	2.00	EA	
	H0511163204	-	075	SCREW, PAN HD CROSSED RECESSED, 6-32 X 1/4, SS	4.00	EA	
	Н3001100600		076	WASHER, FLAT, #6, SS	12.00	EA	
•	H0591163212	-	077	SCREW, CAP, HEX SOCKET, 6-32 X 3/4, SS	6.00	EA	
	900577	В	078	ADHESIVE, LOCTITE 222, THREADLOCKER, SMALL SCREW,	0.00	BT	
	AS REQUIRED H0511183210		080	SCREW, PAN HD CROSSED RECESSED, 8-32 X 5/8, SS	4.00	EA	
	900782	C	081	ADHESIVE, CYANOACRYLATE 910	0.01	вт	
	AS REQUIRED 900620-04	D	082	CLAMP, CABLE, 1/4 DIA, 1/2 W, CELLULOSE	2.00	EA	
	400646-03	G	083	CABLE ASSEMBLY, SENSOR	1.00	EA	
	400646-11	G	084	CABLE ASSEMBLY, SENSOR	1.00	EA	
	400646-12	G	085	CABLE ASSEMBLY, SENSOR	1.00	EA	











Assembly 400583-05	Rev K	Assembly Description ELECTRONIC CHASSIS ASSEMBLY ATX STYLE W/VDO, NTWRK, SND CD				
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
400596	D	001	CHASSIS HARDWARE ASSEMBLY	1.00	EA	
501361	C	002	PLATE, MOUNTING, PCB, SIDE RIGHT	1.00	EA	
501826	C	003	PLATE, MOUNTING, PCB, ATX BOARD, SIDE LEFT	1.00	EA	
501363	C	004	COVER, TOP, ELECTRONICS CHASSIS	1.00	EA	
501355	D	005	BRACKET, SUPPORT, HARD DRIVES	2.00	EA	
450132	D1	006	PCB ASSY, AC POWER DISTRIBUTION PC BOARD	1.00	EA	
450133	B2	007	PCB ASSY, PMT POWER AND FILTER BOARD	1.00	EA	
450150	D3	008	PCB ASSY, POWER DISTRIBUTION BD (ATX STYLE)	1.00	EA	
450101-01	Н1	009	PCB ASSY, SLAVE 0/1 PROCESSOR	1.00	EA	
450101-02	Н1	010	PCB ASSY, SLAVE 2/3 PROCESSOR	1.00	EA	
903920	В	011	MOTHERBOARD, PROX-1650-U	1.00	EA	
450166	A	012	PCB ASSY, 6 SLOT BACKPLANE MOTHERBOARD	1.00	EA	
903605	Α	018	CARD, ROCKET, UNIVERSAL	1.00	EA	
901410	A	019	FILTER, RFI	1.00	EA	
400808-01	D	022	CABLE ASSEMBLY, POWER TO CPU ATX STYLE	1.00	EA	
401240	C	025	CABLE ASSEMBLY, POWER TO MEMORY DEVICES/CPU FANS ATX STYLE	1.00	EA	
400603	D	026	CABLE ASSEMBLY, AC FOR PMT POWER SUPPLY	1.00	EA	
400607	C	029	CABLE ASSEMBLY, AC DISTRIBUTION PC BOARD TO FILTER	1.00	EA	
901412-02	A	030	POST, KEYSLOT	7.00	EA	
H0511144004		031	SCREW, PAN HD CROSSED RECESSED, 4-40 X 1/4, SS	15.00	EA	
H0511163204		032	SCREW, PAN HD CROSSED RECESSED, 6-32 X 1/4, SS	36.00	EA	
H0511183204		033	SCREW, PAN HD CROSSED RECESSED, 8-32 X 1/4, SS	31.00	EA	
H3001100400		034	WASHER, FLAT, #4, SS	15.00	EA	
H3001100600		035	WASHER, FLAT, #6, SS	47.00	EA	
H3001100800		036	WASHER, FLAT, #8, SS	6.00	EA	
H3011100400		037	WASHER, SPLIT LOCK, #4, SS	15.00	EA	
H3011100600		038	WASHER, SPLIT LOCK, #6, SS	43.00	EA	
H3011100800		039	WASHER, SPLIT LOCK, #8, SS	14.00	EA	

Assembly 400583-05	Rev K						
Component	Rev	Item	Component Description	Qty Per Assy	U/M		
450153	В1	040	PCB ASSY, COMMON MEMORY BOARD EURO	1.00	EA		
450115	M	041	PCB ASSY, TEMPERATURE PROCESSOR BOARD	1.00	EA		
400665	C	045	CABLE ASSEMBLY, COMMON MEMORY	1.00	EA		
501414	Α	046	RAIL, CHASSIS	3.00	EA		
400669	E	047	POWER SUPPLY COVER ASSEMBLY	1.00	EA		
900646-01	Α	048	PUSH MOUNT, CONSTANT TENSION, NYLON	2.00	EA		
901588	A	049	STANDOFF, MALE/FEMALE, 1/4 HEX X 1/4 LG, 6-32 S.S.	6.00	EA		
900551-04	C	050	TIE, CABLE, 1.25 INCH BUNDLE DIA, 50 5/8 LG	7.00	EA		
900620-10	C	051	CLAMP, CABLE, 5/8 DIA X 1/2 W, CELLULOSE	1.00	EA		
900620-03	C	052	CLAMP, CABLE, 3/16 DIA X 1/2 W, CELLULOSE	2.00	EA		
H2001103200		053	NUT, HEX, 10-32, SS	3.00	EA		
H3011101000		054	WASHER, SPLIT LOCK, #10, SS	3.00	EA		
H3001101000		055	WASHER, FLAT, #10, SS	3.00	EA		
H3031101000		056	WASHER, EXTERNAL TOOTH LOCK, #10, SS	3.00	EA		
450115-02	M	058	PCB ASSY, CLOT DETECTION BOARD	1.00	EA		
501585	A	059	PLATE, MOUNTING, HARD DRIVE SUPPORT BRACKET	1.00	EA		
902205	C	060	MICROPROCESSOR, PENTIUM III 866 & 933 MHZ, 1.0 GHZ	1.00	EA		
901903	L	061	DRIVE, HARD, X.XX GIGABYTE	3.00	EA		
901756-02	В	072	CORE, SUPPRESSOR, FLAT CABLE, 40 COND.	3.00	EA		
900536	Α	074	CLAMP, CABLE, RIBBON, ADHESIVE BACK, GRAY, 1.09 WIDE	1.00	EA		
501683	A	075	GUARD, DOOR, POWER SUPPLY	1.00	EA		
H0511183208		076	SCREW, PAN HD CROSSED RECESSED, 8-32 X 1/2, SS	1.00	EA		
901746-01	A	077	STRIP, GROMMET, MOLDED	0.00	FT		
H0511163205	REQUIRED	083	SCREW, PAN HD CROSSED RECESSED, 6-32 X 5/16, SS	4.00	EA		
401330	В	087	COMPUTER ASSEMBLY, SINGLE BOARD	1.00	EA		
901967	A	088	MODULE, MEMORY, SDRAM 128 MB, PC100 W/ECC	1.00	EA		
900706-02	C	089	TIE, CABLE, 17.5 IN NYLON	1.00	EA		
400805	A	090	CABLE ASSEMBLY, 24V AC ATX STYLE	1.00	EA		

Bill of Materials

2/3/2005

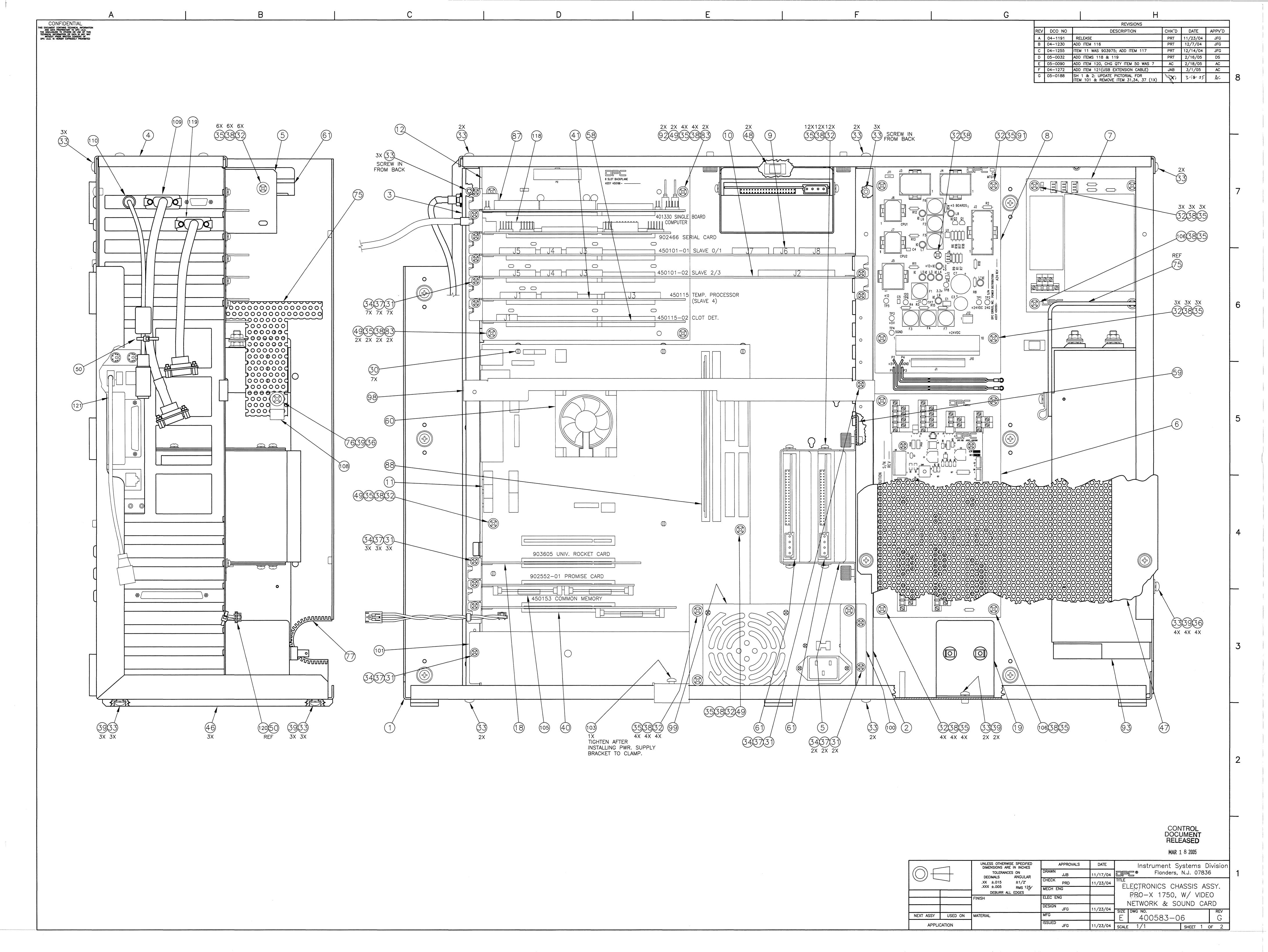
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H3031100600		091	WASHER, EXTERNAL TOOTH LOCK, #6, SS	1.00	EA	_
H2001163200		092	NUT, HEX, 6-32, SS	2.00	EA	
401238	В	093	POWER SUPPLY ASSEMBLY, PRO-X ATX	1.00	EA	
400873	Α	094	CABLE ASSEMBLY, +5VDC POWER SUPPLY TERMINALS TO I/O PANEL	1.00	EA	
600288	В	096	PROCD, INSTL INSTR INTEL MOTHERBOARD IMM 2000	0.01	EA	
REFERENCE 500542	Α	097	LABEL, GROUND SYMBOL	1.00	EA	
300342	Λ	097	LABEL, GROUND STRIBUL	1.00	LA	
503066	A	098	BRACKET, SUPPORT, ELECTRONIC CHASSIS	1.00	EA	
401237	F	099	POWER SUPPLY ASSEMBLY, ATX	1.00	EA	
503236	В	100	BRACKET, RIGHT SIDE COMPUTER POWER SUPPLY ELE CHASSIS	1.00	EA	
503235	В	101	BRACKET, LEFT SIDE COMPUTER POWER SUPPLY ELE CHASSIS	1.00	EA	
H0511183212		103	SCREW, PAN HD CROSSED RECESSED, 8-32 X 3/4, SS	1.00	EA	
401249	В1	104	CORD SET AC ASSEMBLY	1.00	EA	
902552-01	Α	105	SOFTWARE, FAST TRAK 100, PROMISE CARD	1.00	EA	
H0511163206		106	SCREW, PAN HD CROSSED RECESSED, 6-32 X 3/8, SS	6.00	EA	
H0511183206		107	SCREW, PAN HD CROSSED RECESSED, 8-32 X 3/8, SS	1.00	EA	
900620-06	C	108	CLAMP, CABLE, 3/8 DIA X 1/2 W, CELLULOSE	1.00	EA	
401355	В	109	CABLE ASSEMBLY, VIDEO EXTENSION	1.00	EA	
902861	Α	110	CABLE, MOUSE/KEYBOARD EXTENSION 6"	1.00	EA	
450288	D	111	PCB ASSY, SHAKER MOTOR DRIVER 61Hz	1.00	EA	
901534-15	В	115	STANDOFF, 1/4 HEX, FEMALE, 6-32	4.00	EA	
902466	C	118	CARD, SERIAL, MP5507	1.00	EA	
401321	D	119	CABLE ASSEMBLY, SERIAL CARD TO I/O (2K) SMS	1.00	EA	

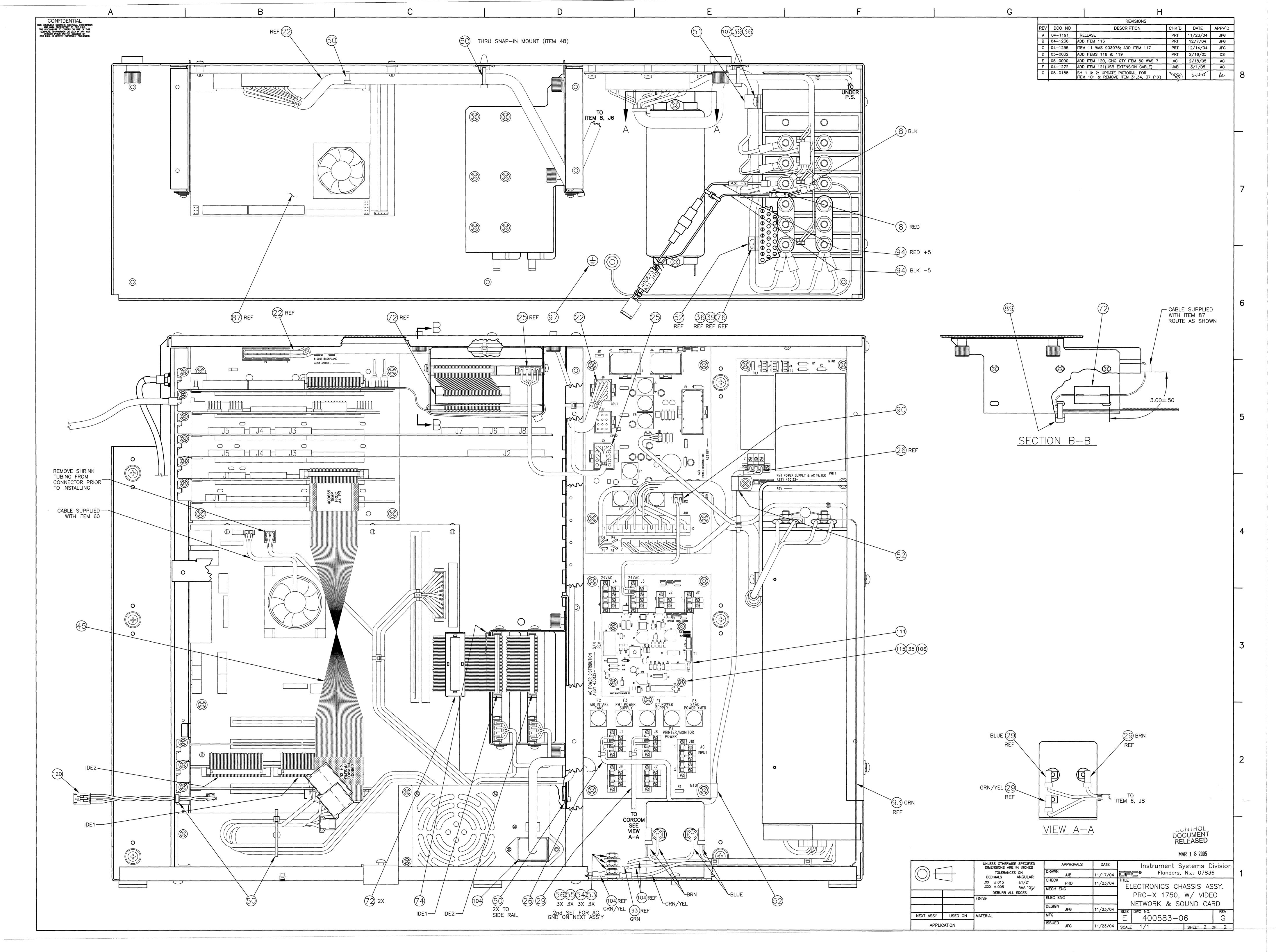
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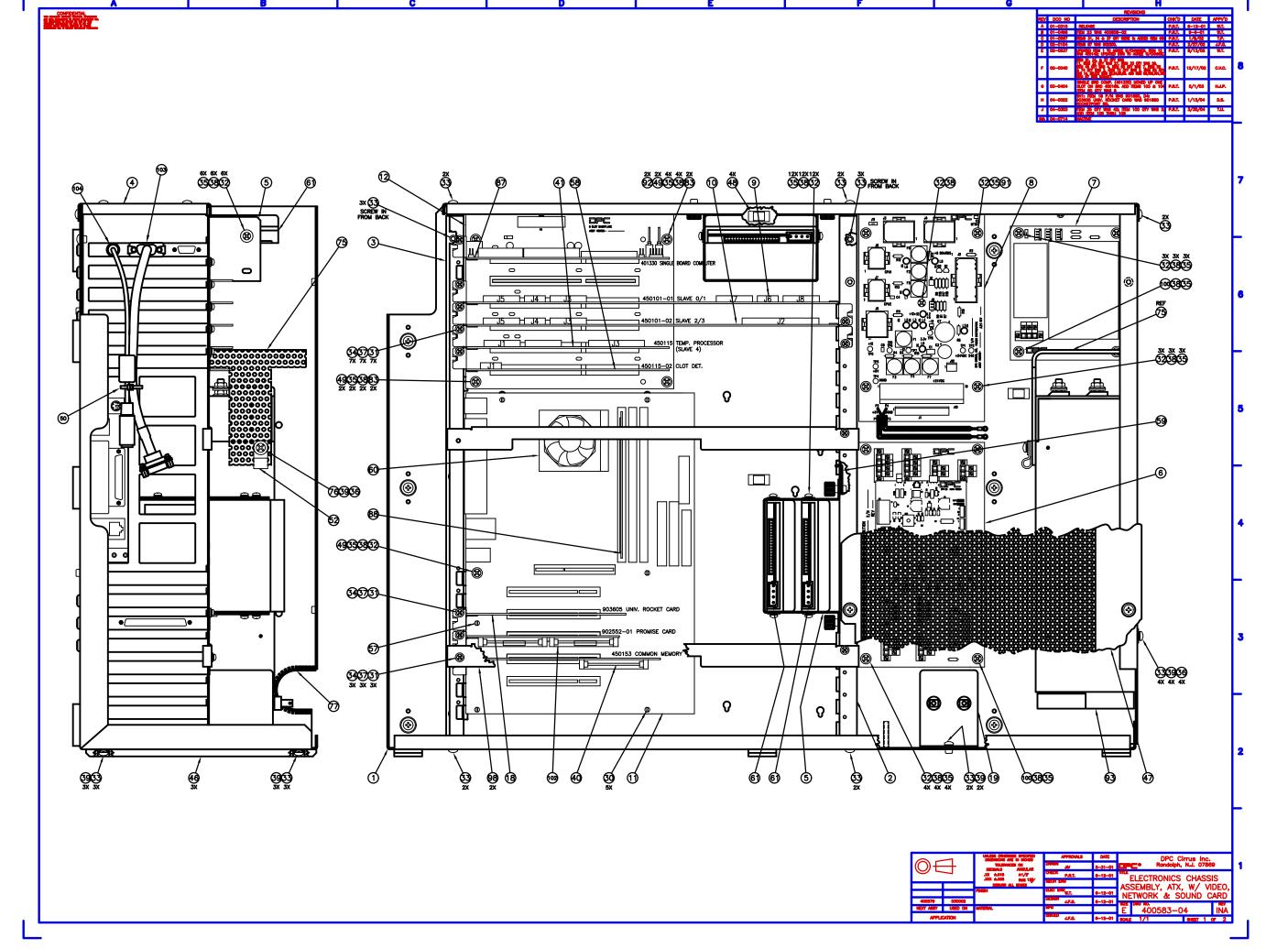
Assembly 400583-06	Rev G	E	ssembly Description LECTRONIC CHASSIS ASSEMBLY PRO-X STYLE W/	VDO,	
Component	Rev	Item	TWRK, SND CD Component Description	Qty Per Assy	U/M
400596	D	001	CHASSIS HARDWARE ASSEMBLY	1.00	EA
501361	C	002	PLATE, MOUNTING, PCB, SIDE RIGHT	1.00	EA
501826	C	003	PLATE, MOUNTING, PCB, ATX BOARD, SIDE LEFT	1.00	EA
501363	C	004	COVER, TOP, ELECTRONICS CHASSIS	1.00	EA
501355	D	005	BRACKET, SUPPORT, HARD DRIVES	2.00	EA
450132	D1	006	PCB ASSY, AC POWER DISTRIBUTION PC BOARD	1.00	EA
450133	B2	007	PCB ASSY, PMT POWER AND FILTER BOARD	1.00	EA
450150	D3	008	PCB ASSY, POWER DISTRIBUTION BD (ATX STYLE)	1.00	EA
450101-01	HI	009	PCB ASSY, SLAVE 0/1 PROCESSOR	1.00	EA
450101-02	Н1	010	PCB ASSY, SLAVE 2/3 PROCESSOR	1.00	EA
401894	В	011	MOTHERBOARD, PRO-X 1750-G2 ASSEMBLY	1.00	EA
450166	Α	012	PCB ASSY, 6 SLOT BACKPLANE MOTHERBOARD	1.00	EA
903605	Α	018	CARD, ROCKET, UNIVERSAL	1.00	EA
901410	A	019	FILTER, RFI	1.00	EA
400808-01	D	022	CABLE ASSEMBLY, POWER TO CPU ATX STYLE	1.00	EA
401240	C	025	CABLE ASSEMBLY, POWER TO MEMORY DEVICES/CPU FANS ATX STYLE	1.00	EA
400603	D	026	CABLE ASSEMBLY, AC FOR PMT POWER SUPPLY	1.00	EA
400607	C	029	CABLE ASSEMBLY, AC DISTRIBUTION PC BOARD TO FILTER	1.00	EA
901412-02	A	030	POST, KEYSLOT	7.00	EA
H0511144004		031	SCREW, PAN HD CROSSED RECESSED, 4-40 X 1/4, SS	14.00	EA
H0511163204	*	032	SCREW, PAN HD CROSSED RECESSED, 6-32 X 1/4, SS	36.00	EA
H0511183204		033	SCREW, PAN HD CROSSED RECESSED, 8-32 X 1/4, SS	31.00	EA
H3001100400		034	WASHER, FLAT, #4, SS	14.00	EA
H3001100600		035	WASHER, FLAT, #6, SS	47.00	EA
H3001100800		036	WASHER, FLAT, #8, SS	6.00	EA
H3011100400		037	WASHER, SPLIT LOCK, #4, SS	14.00	EA
H3011100600		038	WASHER, SPLIT LOCK, #6, SS	43.00	EA
H3011100800		039	WASHER, SPLIT LOCK, #8, SS	14.00	EA

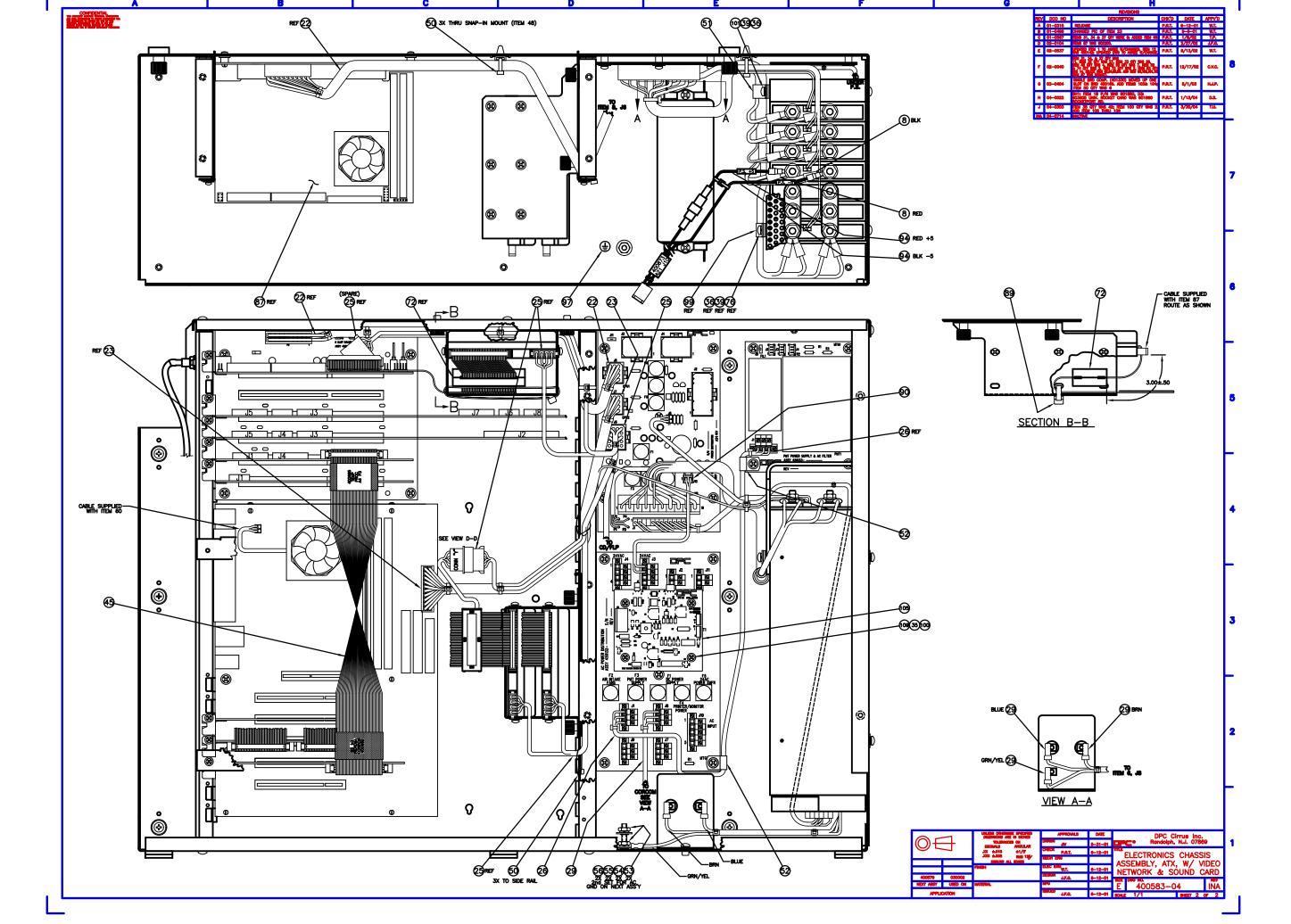
Assembly 400583-06		Rev G						
	Component	Rev	Item	Component Description	Qty Per Assy	U/M		
	450153	B1	040	PCB ASSY, COMMON MEMORY BOARD EURO	1.00	EA		
	450115	M	041	PCB ASSY, TEMPERATURE PROCESSOR BOARD	1.00	EA		
	400665	C	045	CABLE ASSEMBLY, COMMON MEMORY	1.00	EA		
	501414	A	046	RAIL, CHASSIS	3.00	EA		
	400669	E	047	POWER SUPPLY COVER ASSEMBLY	1.00	EA		
	900646-01	A	048	PUSH MOUNT, CONSTANT TENSION, NYLON	2.00	EA		
	901588	Α	049	STANDOFF, MALE/FEMALE, 1/4 HEX X 1/4 LG, 6-32 S.S.	6.00	EA		
	900551-04	С	050	TIE, CABLE, 1.25 INCH BUNDLE DIA, 50 5/8 LG	8.00	EA		
	900620-10	C	051	CLAMP, CABLE, 5/8 DIA X 1/2 W, CELLULOSE	1.00	EA		
	900620-03	C	052	CLAMP, CABLE, 3/16 DIA X 1/2 W, CELLULOSE	2.00	EA		
	H2001103200		053	NUT, HEX, 10-32, SS	3.00	EA		
	H3011101000		054	WASHER, SPLIT LOCK, #10, SS	3.00	EA		
	H3001101000		055	WASHER, FLAT, #10, SS	3.00	EA		
	H3031101000		056	WASHER, EXTERNAL TOOTH LOCK, #10, SS	3.00	EA		
	450115-02	M	058	PCB ASSY, CLOT DETECTION BOARD	1.00	EA		
	501585	Α	059	PLATE, MOUNTING, HARD DRIVE SUPPORT BRACKET	1.00	EA		
	903973	Α	060	PROCESSOR, PENTIUM 4, 2 GHz	1.00	EA		
	901903	L	061	DRIVE, HARD, X.XX GIGABYTE	3.00	EA		
	901756-02	В	072	CORE, SUPPRESSOR, FLAT CABLE, 40 COND.	3.00	EA		
	900536	Α	074	CLAMP, CABLE, RIBBON, ADHESIVE BACK, GRAY, 1.09	1.00	EA		
	501683	Α	075	WIDE GUARD, DOOR, POWER SUPPLY	1.00	EA		
	H0511183208		076	SCREW, PAN HD CROSSED RECESSED, 8-32 X 1/2, SS	1.00	EA		
	901746-01	Α	077	STRIP, GROMMET, MOLDED	0.00	FT		
	FEET AS REQUIRED H0511163205		083	SCREW, PAN HD CROSSED RECESSED, 6-32 X 5/16, SS	4.00	EA		
	401330	В	087	COMPUTER ASSEMBLY, SINGLE BOARD	1.00	EA		
	903974	A	088	MODULE, MEMORY, DDRAM 256 MB	1.00	EA		
	900706-02	C	089	CABLE TIE, 17.5 INCH, NYLON	1.00	EA		
	400805	A	090	CABLE ASSEMBLY, 24V AC ATX STYLE	1.00	EA		

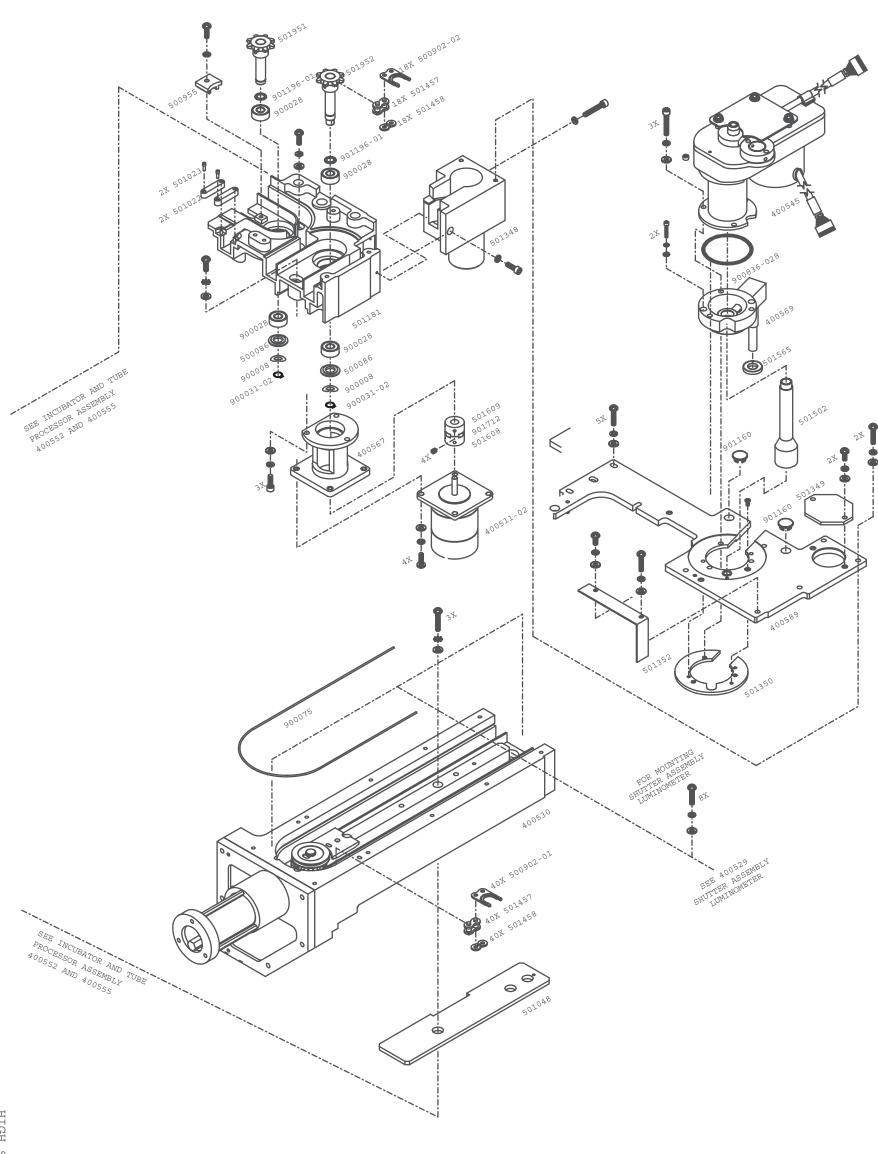
	Assembly 400583-06	Rev G	E	Assembly Description ELECTRONIC CHASSIS ASSEMBLY PRO-X STYLE W/VDO, NTWRK, SND CD				
	Component	Rev	Item	Component Description	Qty Per Assy	U/M		
Ī	H3031100600		091	WASHER, EXTERNAL TOOTH LOCK, #6, SS	1.00	EA		
	H2001163200		092	NUT, HEX, 6-32, SS	2.00	EA		
	401238	В	093	POWER SUPPLY ASSEMBLY, PRO-X ATX	1.00	EA		
	400873	Α	094	CABLE ASSEMBLY, +5VDC POWER SUPPLY TERMINALS TO I/O PANEL	1.00	EA		
	600288	В	096	PROCD, INSTL INSTR INTEL MOTHERBOARD IMM 2000	0.01	EA		
	REFERENCE 500542	Α	097	LABEL, GROUND SYMBOL	1.00	EA		
	503066	A	098	BRACKET, SUPPORT, ELECTRONIC CHASSIS	1.00	EA		
	401237	F	099	POWER SUPPLY ASSEMBLY, ATX	1.00	EA		
	503236	В	100	BRACKET, RIGHT SIDE COMPUTER POWER SUPPLY ELE CHASSIS	1.00	EA		
	503235	C	101	BRACKET, LEFT SIDE COMPUTER POWER SUPPLY ELE CHASSIS	1.00	EA		
	H0511183212		103	SCREW, PAN HD CROSSED RECESSED, 8-32 X 3/4, SS	1.00	EA		
	401249	В1	104	CORD SET AC ASSEMBLY	1.00	EA		
	902552-01	A	105	SOFTWARE, FAST TRAK 100, PROMISE CARD	1.00	EA		
	H0511163206		106	SCREW, PAN HD CROSSED RECESSED, 6-32 X 3/8, SS	6.00	EA		
	H0511183206		107	SCREW, PAN HD CROSSED RECESSED, 8-32 X 3/8, SS	1.00	EA		
	900620-06	C	108	CLAMP, CABLE, 3/8 DIA X 1/2 W, CELLULOSE	1.00	EA		
	401355	В	109	CABLE ASSEMBLY, VIDEO EXTENSION	1.00	EA		
	902861	Α	110	CABLE, MOUSE/KEYBOARD EXTENSION 6"	1.00	EA		
	450288	D	111	PCB ASSY, SHAKER MOTOR DRIVER 61Hz	1.00	EA		
	901534-15	В	115	STANDOFF, 1/4 HEX, FEMALE, 6-32	4.00	EA		
	600705 REF DOCUMENT	Α	116	PROCD, BIOS SETTINGS PROX-1750 IMM 2000	0.01	EA		
	472204-0009 REFERENCE	C	117	SOFTWARE, VR 4.3 IMM 2000 GHOST USER/CONTROL	0.01	EA		
	902466	C	118	CARD, SERIAL, MP5507	1.00	EA		
	401321	D	119	CABLE ASSEMBLY, SERIAL CARD TO I/O (2K) SMS	1.00	EA		
	400818	Α	120	CABLE ASSEMBLY, CD SOUND ATX STYLE	1.00	EA		
	904023	A	121	CABLE, USB EXTENTION, 1M LG	1.00	EA		





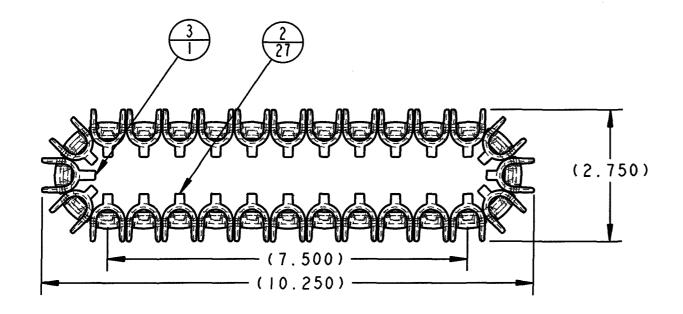


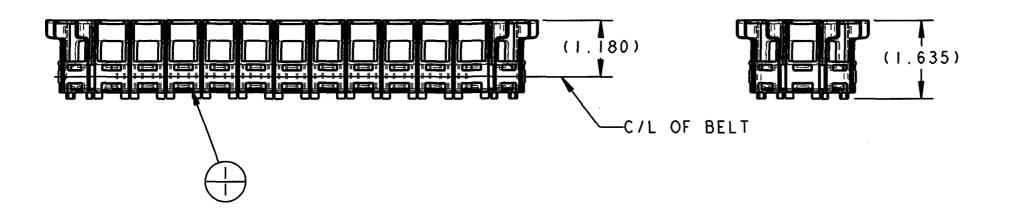




HIGH SPEED SPINNER
AND LUMINOMETER ASSEMBLY
400645 AND 400530

		REVISIONS			
REV	DCO NO	DESCRIPTION	CHKD	DATE	APPD
1	P01381	BB RELEASE	ł M	11-14-01	TP
Α	02-1020	RELEASE	.M. 2	7-20-03	7.f.



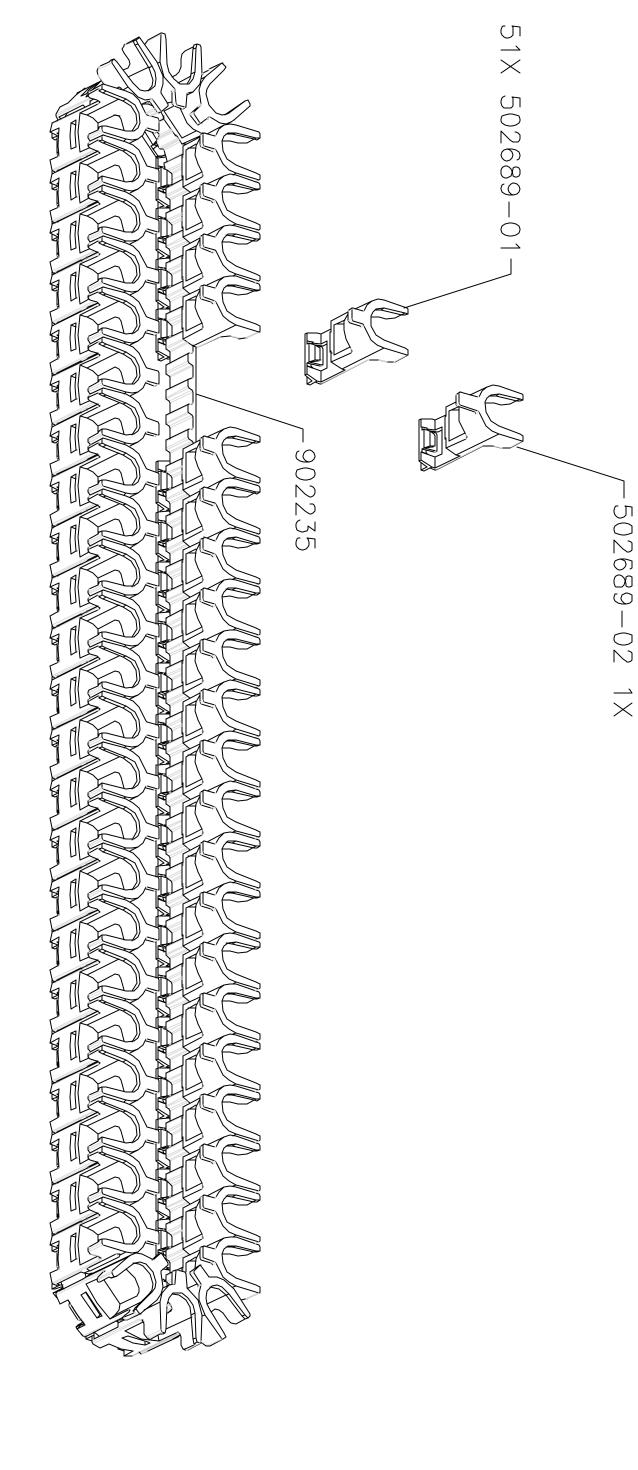


CONTROL DOCUMENT RELEASED

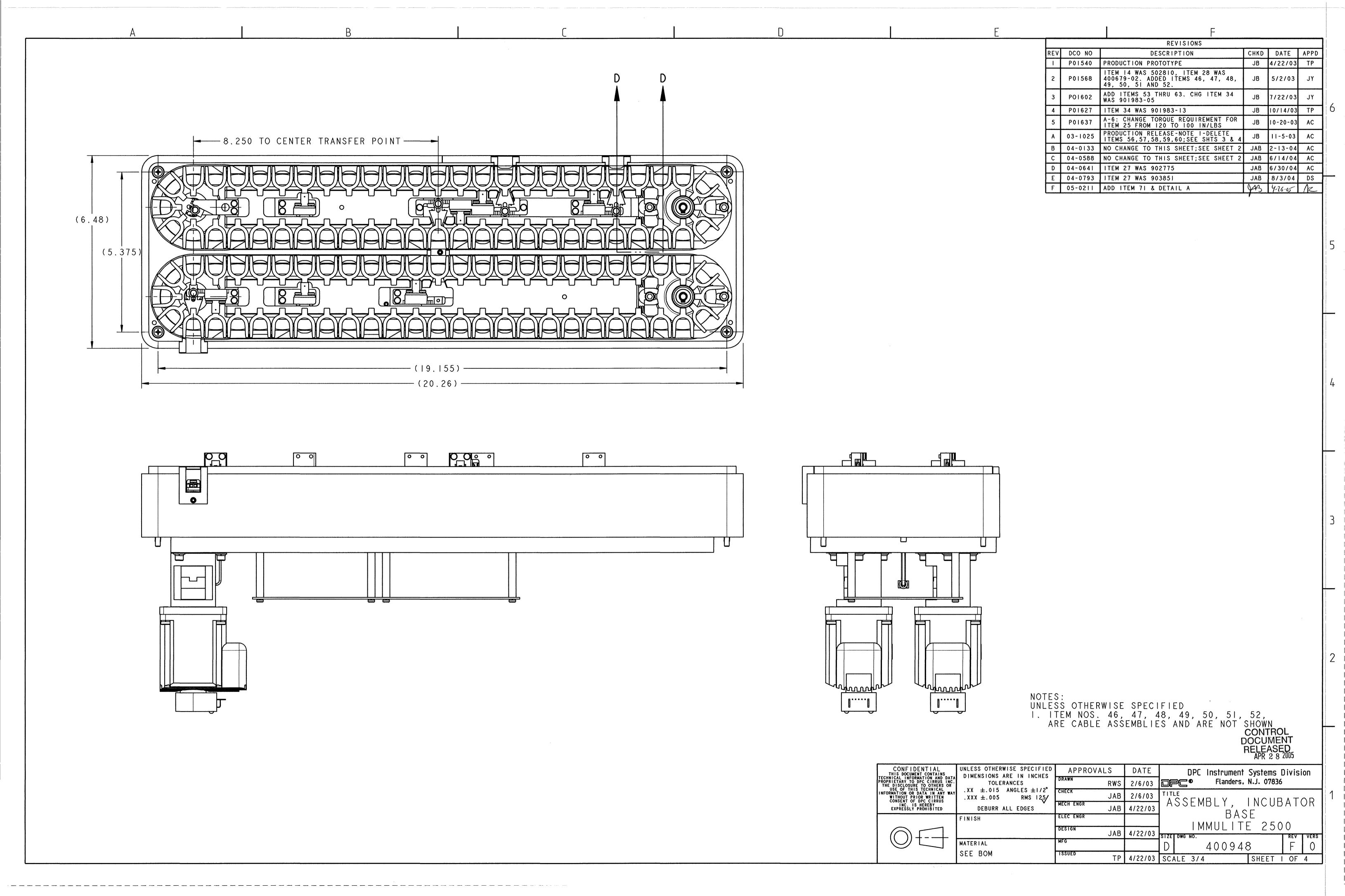
APR 0 4 2005

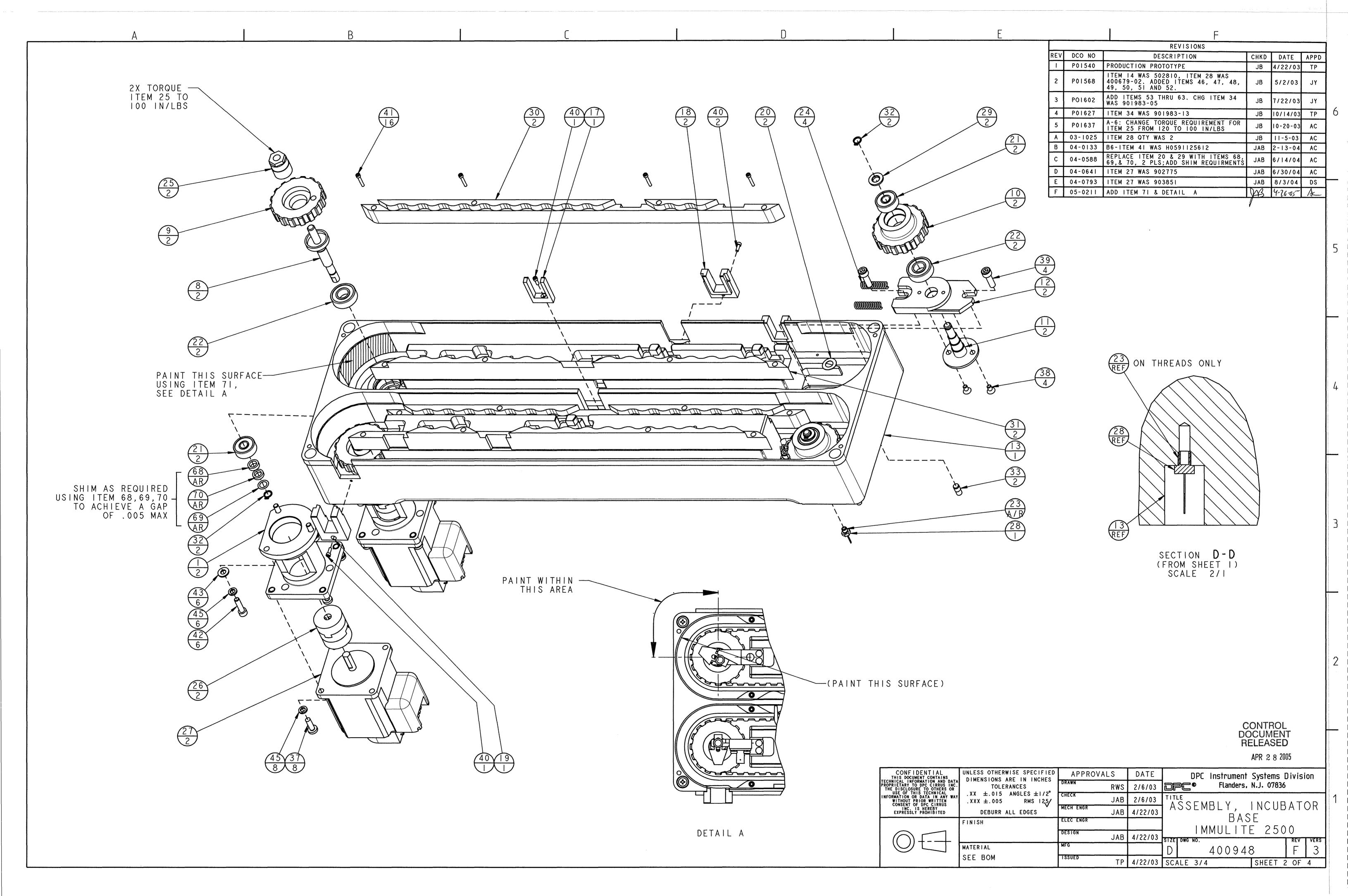
		ODICIMAL			APR 0 4 2005	
CONFIDENTIAL THIS DOCUMENT CONTAINS TECHNICAL INFORMATION AND DATA	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES	APPROVALS	DATE		Systems Division , N.J. 07836	
PROPRIETARY TO DPC CIRRUS INC. THE DISCLOSURE TO OTHERS OR USE OF THIS TECHNICAL INFORMATION OR DATA IN ANY WAY WITHOUT PRIOR WRITTEN	.XX ±.015 ANGLES ±1/2° .XXX ±.005 RMS 125/	DRAWN CAT	9-24-01	TITLE	, N.J. 01030	
		CHECK	11-6-01	BELT ASSEMBLY		
CONSENT OF DPC CIRRUS INC. IS HEREBY	FINISH	MECH ENGR. MALYAROV	TENCK MALYAROV 11-6-01			
EXPRESSLY PROHIBITED		ELEC ENGR		T LUMINOMETER		
		DESIGN		SIZE DWG NO.	REV VERS	
	MATERIAL SEE BOM	MFG		B 40094	I A [O]	
		ISSUED T.PALMIERI	11-14-01	SCALE 1/2	SHEET I OF I	

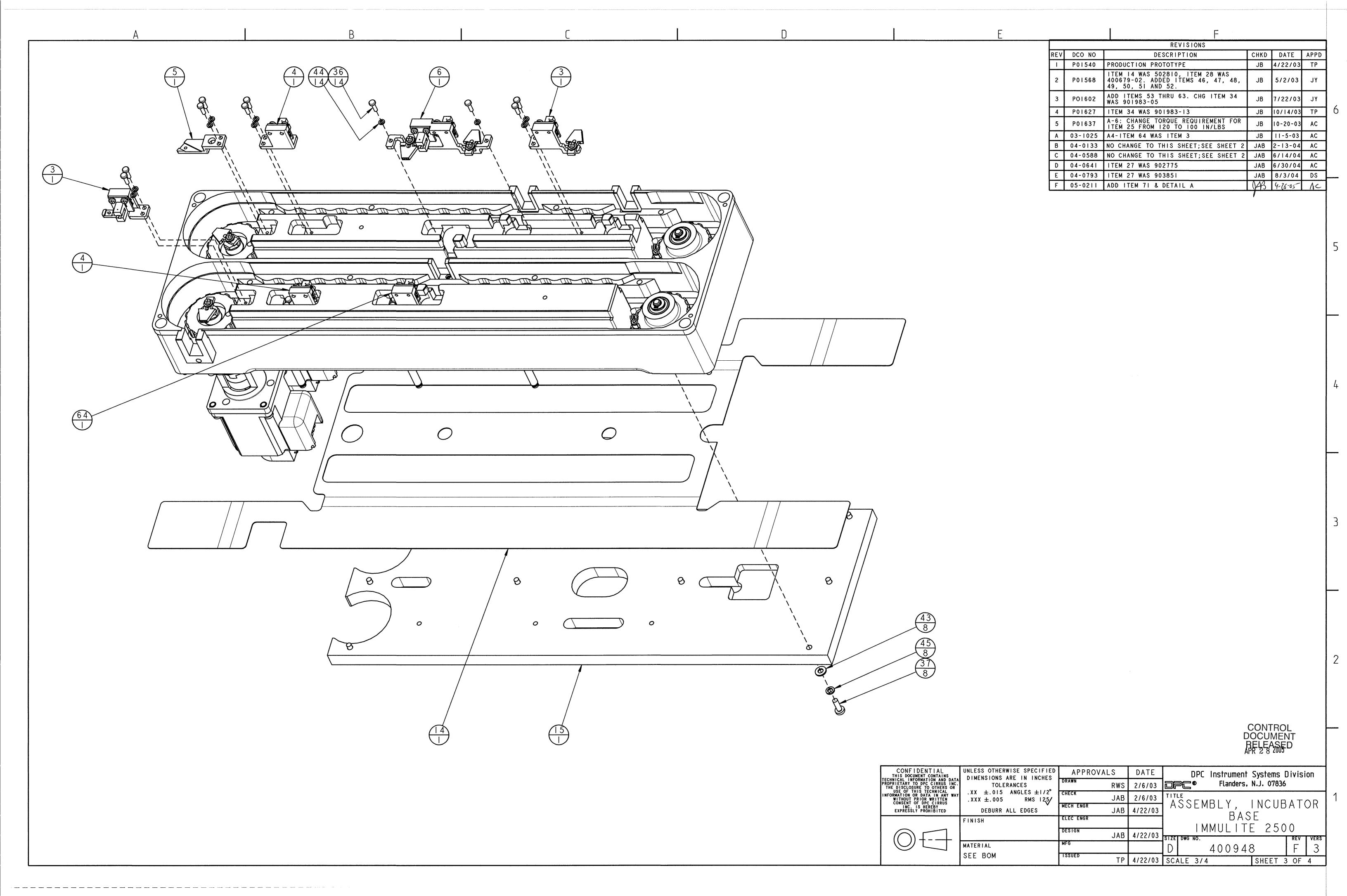
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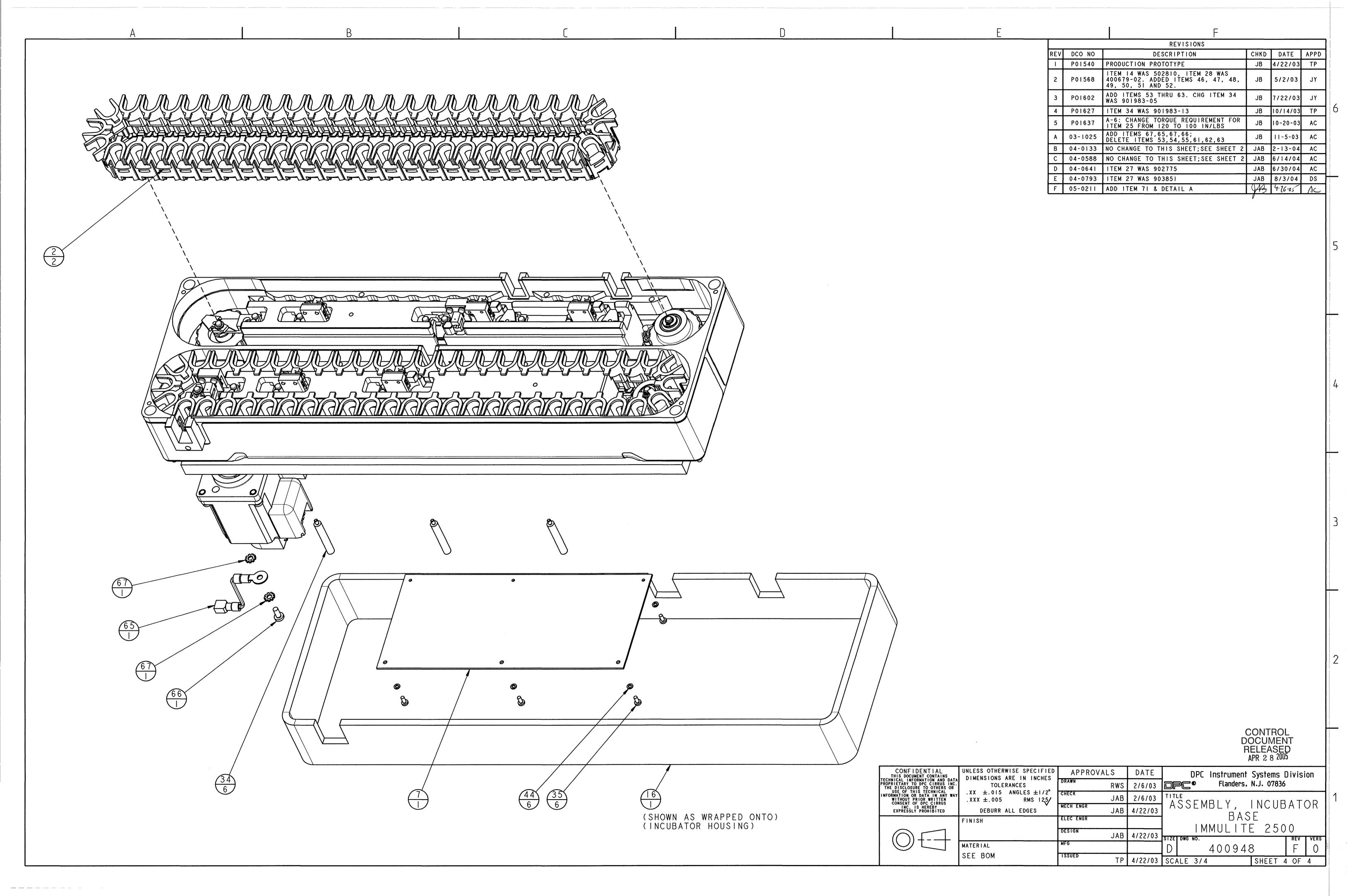


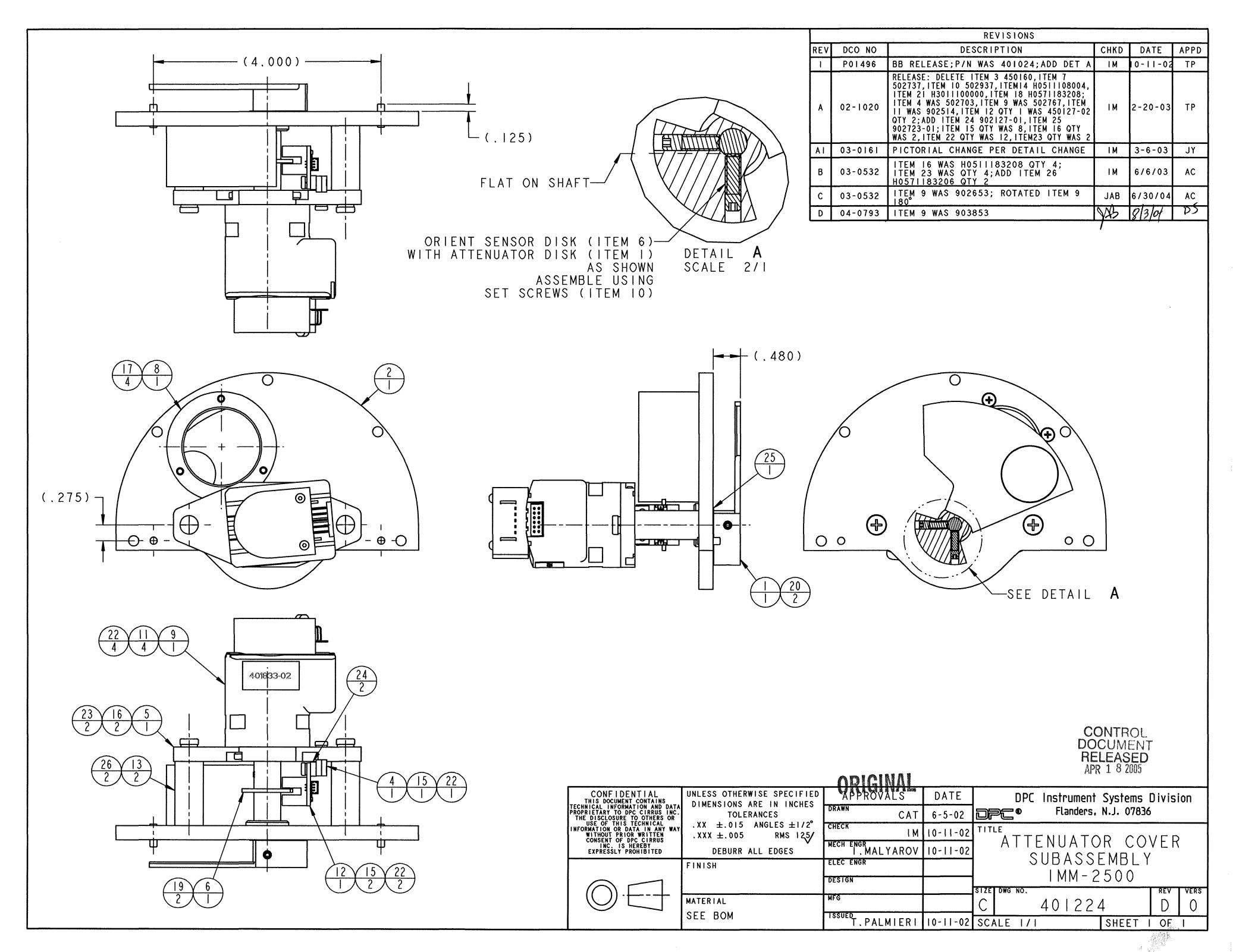
INCUBATOR BELT ASSEMBLY 400947

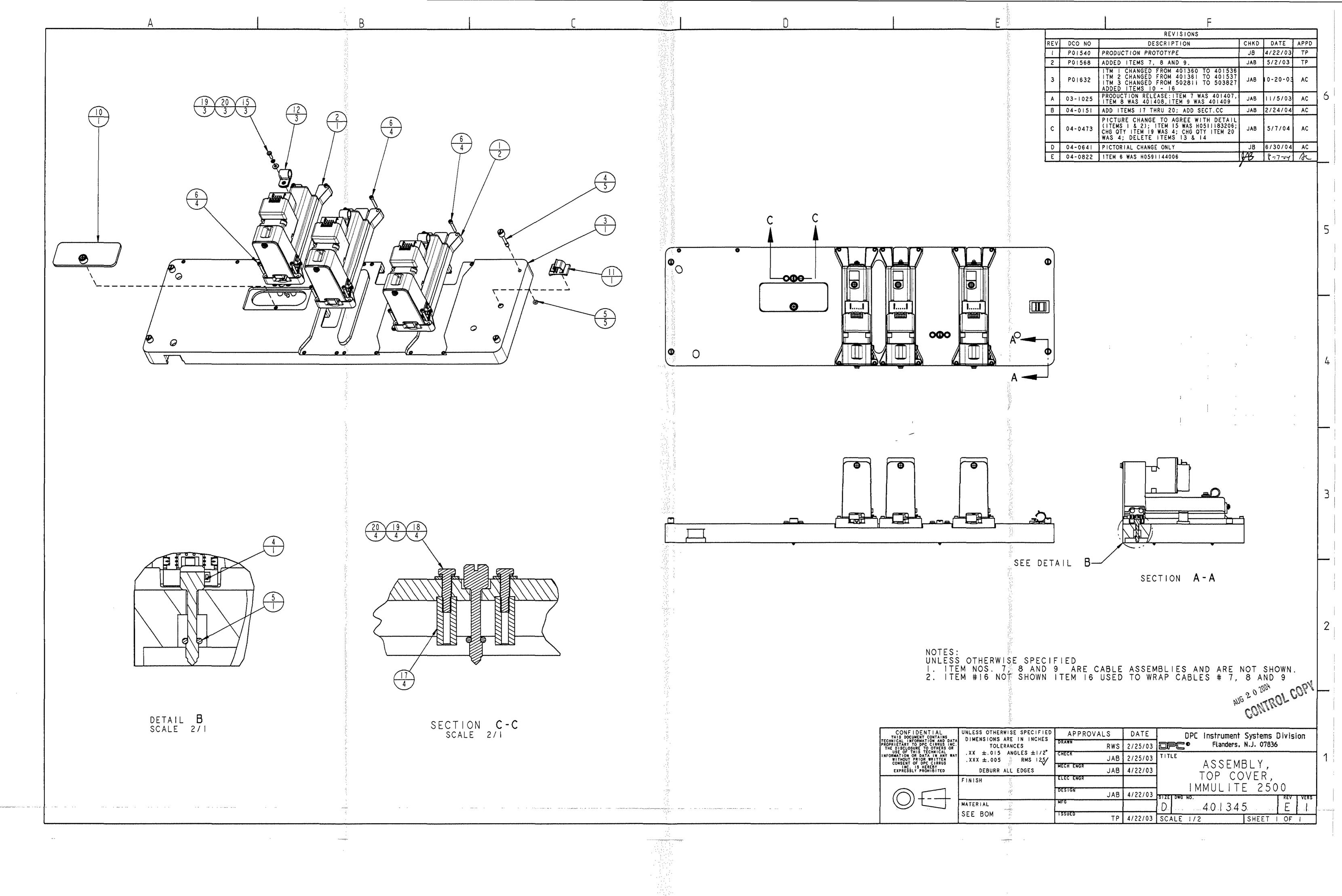












Component			VASH STATION ASSEMBLY IMM 2500			
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
401927	A	001	DRIVE SHAFT ASSEMBLY	1.00	EA	•
401961	Α	002	SUMP ASSEMBLY	1.00	EA	
450186	D	003	PCB ASSY, OPTO SENSOR	1.00	EA	
503509	Α	004	LEAD SCREW AND NUT, 1/4" DIA X 1/4" LEAD	1.00	EA	
504553	Α	005	HOUSING, SPIN/WASH STATION	1.00	EA	
504527	Α	006	PLATFORM, REACTION TUBE	1.00	EA	
504526	Α	008	CARRIAGE, SPIN MOTOR	1.00	EA	
503526	Α	009	BLOCK, MOUNTING, LIFT MOTOR	1.00	EA	
503528	Α	011	BUSHING, LEAD SCREW	1.00	EA	
503529	Α	012	FLAG, HOME POSITION	1.00	EA	
503702	В	013	RAMP, REACTION TUBE	2.00	EA	
503540	Α	014	WASHER, SHOULDERED	1.00	EA	
502852	В	015	PULLEY, MODIFIED	1.00	EA	
502853	В	016	PULLEY, MODIFIED	1.00	EA	
900382	A1	017	WASHER, CURVED, S.S., #10 SCREW	1.00	EA	
902257	Α	019	CLAMP, SHAFT COLLAR, 1/4 ID	2.00	EA	
401455	D	020	WASH MOTOR ASSEMBLY	1.00	EA	
904065	Α	021	SLIDE, PRECISION 200MM, 2 CARRIAGE	1.00	EA	
903580	Α	022	COUPLING, FLEXIBLE BEAM, 1/4 X 1/4 BORE, BALANCED	1.00	EA	
902762	A2	024	BEARING, FLG, .1875 ID X .375 OD X .125 W, SS	2.00	EA	
902763	В	025	BELT, TIMING, .080 PITCH, 42 TEETH	1.00	EA	
904069	Α	026	SPRING, COMPRESSION, 1.172 OD X 2.32 LG X .057 W	1.00	EA	
902981	Α	027	SPRING, COMPRESSION, .480 OD X 1.00 LG X .051 WD	1.00	EA	
902769	Α	029	SCREW, SOCKET HD, CAP, M3 X 4MM LG	8.00	EA	
902770	Α	030	SCREW, SOCKET HD, CAP, M3 X 6MM LG	4.00	EA	
401831-01	В	031	MOTOR ASSEMBLY, PROGRAMMED, TUBE LIFTER 1 & 2	1.00	EA	
900734-15	D	032	RING, RETAINING, EXTERNAL, 3/16 SHAFT	2.00	EA	
H0511125604	-	035	SCREW, PAN HD CROSSED RECESSED, 2-56 X 1/4, SS	4.00	EA	
	401961 450186 503509 504553 504527 504526 503528 503529 503702 503540 502852 502853 900382 902257 401455 904065 903580 902762 902763 904069 902981 902769 902770 401831-01 900734-15	401927 A 401961 A 450186 D 503509 A 504553 A 504527 A 504526 A 503526 A 503528 A 503529 A 503702 B 503702 B 503540 A 502852 B 502853 B 900382 A1 902257 A 401455 D 904065 A 903580 A 902762 A2 902763 B 904069 A 902981 A 902769 A 902770 A 401831-01 B 9000734-15 D	401927 A 001 401961 A 002 450186 D 003 503509 A 004 504553 A 005 504527 A 006 504526 A 008 503526 A 009 503528 A 011 503529 A 012 503702 B 013 503540 A 014 502852 B 015 502853 B 016 900382 A1 017 902257 A 019 401455 D 020 904065 A 021 903580 A 022 902762 A2 024 902763 B 025 904069 A 026 902981 A 027 902769 A 029 902770 A 030 401831-01 B 031 900734-15 D 032	401927 A 001 DRIVE SHAFT ASSEMBLY 401961 A 002 SUMP ASSEMBLY 450186 D 003 PCB ASSY, OPTO SENSOR 503509 A 004 LEAD SCREW AND NUT, 1/4" DIA X 1/4" LEAD 504553 A 005 HOUSING, SPIN/WASH STATION 504527 A 006 PLATFORM, REACTION TUBE 504526 A 008 CARRIAGE, SPIN MOTOR 503528 A 011 BUSHING, LEAD SCREW 503529 A 012 FLAG, HOME POSITION 503702 B 013 RAMP, REACTION TUBE 503540 A 014 WASHER, SHOULDERED 502852 B 015 PULLEY, MODIFIED 502853 B 016 PULLEY, MODIFIED 502853 B 016 PULLEY, MODIFIED 502857 A 019 CLAMP, SHAFT COLLAR, 1/4 ID 401455 D 020 WASH MOTOR ASSEMBLY 904065 A 021 SLIDE, PRECISION 200MM, 2 CARRIAGE 903580 A 022 COUPLING, FLEXIBLE BEAM, 1/4 X 1/4 BORE, BALANCED 902762 A2 024 BEARING, FLG, .1875 ID X .375 OD X .125 W, SS 902763 B 025 BELT, TIMING, .080 PITCH, 42 TEETH 904069 A 026 SPRING, COMPRESSION, .150 OD X 1.00 LG X .051 WD 902770 A 030 SCREW, SOCKET HD, CAP, M3 X 4MM LG 902770 A 030 SCREW, SOCKET HD, CAP, M3 X 4MM LG 401831-01 B 031 MOTOR ASSEMBLY, PROGRAMMED, TUBE LIFTER 1 & 2 900734-15 D 032 RING, RETAINING, EXTERNAL, 3/16 SHAFT	401927	401927 A 001 DRIVE SHAFT ASSEMBLY 1.00 EA 401961 A 002 SUMP ASSEMBLY 1.00 EA 450186 D 003 PCB ASSY, OPTO SENSOR 1.00 EA 503509 A 004 LEAD SCREW AND NUT, 14" DIA X 1/4" LEAD 1.00 EA 504533 A 005 HOUSING, SPIN-WASH STATION 1.00 EA 504527 A 006 PLATFORM, REACTION TUBE 1.00 EA 504526 A 008 CARRIAGE, SPIN MOTOR 1.00 EA 503526 A 009 BLOCK, MOUNTING, LIFT MOTOR 1.00 EA 503528 A 011 BUSHING, LEAD SCREW 1.00 EA 503529 A 012 FLAG, HOME POSITION 1.00 EA 503702 B 013 RAMP, REACTION TUBE 2.00 EA 503540 A 014 WASHER, SHOULDERED 1.00 EA 502852 B 015 PULLEY, MODIFIED 1.00 EA 502853 B 016 PULLEY, MODIFIED 1.00 EA 502853 B 016 PULLEY, MODIFIED 1.00 EA 602852 A 019 CLAMP, SHAFT COLLAR, 1/4 ID 2.00 EA 60455 A 021 SLIDE, PRECISION 20MM, 2 CARRIAGE 1.00 EA 60455 A 021 SLIDE, PRECISION 20MM, 2 CARRIAGE 1.00 EA 60465 A 021 SLIDE, PRECISION 20MM, 2 CARRIAGE 1.00 EA 604665 A 022 COUPLING, FLEXIBLE BEAM, 1/4 X 1/4 BORE, BALANCED 1.00 EA 604669 A 026 SPRING, COMPRESSION, 1172 OD X 122 EV, SS 2.00 EA 604069 A 026 SPRING, COMPRESSION, 1172 OD X 122 EV, SS 2.00 EA 604069 A 026 SPRING, COMPRESSION, 180 OD X 1.00 LG X .051 WD 1.00 EA 604081-01 B 031 MOTOR ASSEMBLY, PROGRAMMED, TUBE LIFTER 1 & 2 60504-15 D 032 RING, RETAINING, EXTERNAL, 3/16 SHAFT 2.00 EA 607074-15 D 032 RING, RETAINING, EXTERNAL, 3/16 SHAFT 2.00 EA 607074-15 D 032 RING, RETAINING, EXTERNAL, 3/16 SHAFT 2.00 EA

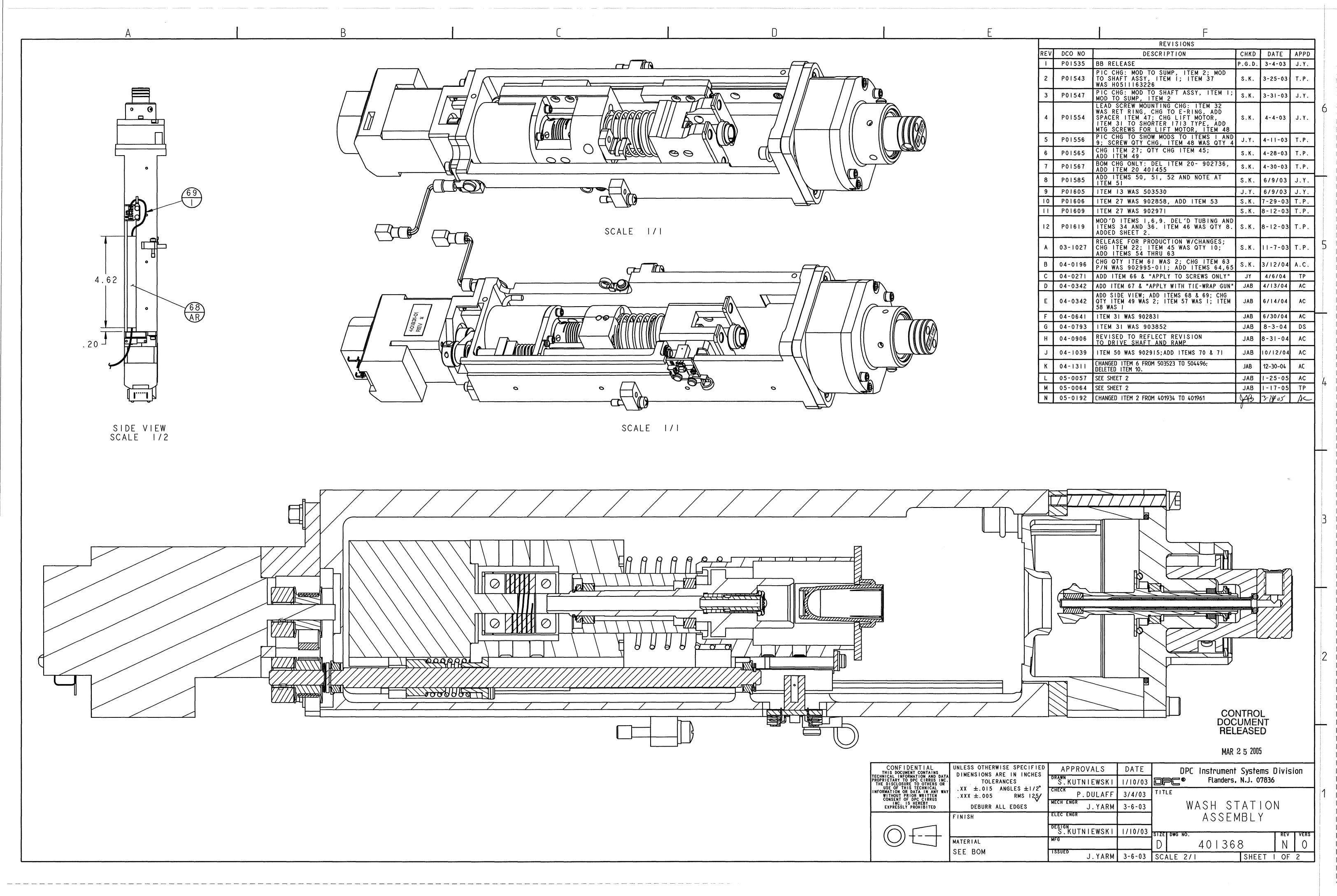
Assembly 401368	Rev N	A V				
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
H0591163224	8	037	SCREW, CAP, HEX SOCKET, 6-21 X 1 1/2, SS	2.00	EA	_
H0571044004	*	038	SCREW, FLAT HD, 4-40 X 1/4	4.00	EA	
H0591144005		039	SCREW, CAP, HEX SOCKET, 4-40 X 5/16, SS	4.00	EA	
H0591163206		041	SCREW, CAP, HEX SOCKET, 6-32 X 3/8, SS	3.00	EA	
H3001100200		042	WASHER, FLAT, #2, SS	2.00	EA	
H3001100600		043	WASHER, FLAT, #6, SS	5.00	EA	
H3011100200		044	WASHER, SPLIT LOCK, #2, SS	4.00	EA	
H3011100400		045	WASHER, SPLIT LOCK, #4, SS	7.00	EA	
H3011100600		046	WASHER, SPLIT LOCK, #6, SS	7.00	EA	
901717	A1	047	SPACER, SHAFT, .188 ID X .016 THK, S.S.	1.00	EA	
900578	Α	048	SCREW, CAP, HEX SOCKET, M3-0.5 X 8 MM LG, S.S.	3.00	EA	
H0511144004		049	SCREW, PAN HD CROSSED RECESSED, 4-40 X 1/4, SS	1.00	EA	
902737-02	C	050	SCREW, CAPTIVE, 8-32 X 13/16 LG	2.00	EA	
900790-84	C	051	WASHER, FLAT, .220 OD X .115 ID X .010 THK, NYLON, BLACK	2.00	EA	
H3011100800		052	WASHER, SPLIT LOCK, #8, SS	2.00	EA	
401378	C	055	WATER DELIVERY TUBE ASSEMBLY IMM 2500/IMM 3000	1.00	EA	
400722-02	E	056	CABLE ASSEMBLY, GROUND STRAP	1.00	EA	
901775	Α	057	CABLE TIE, .75 DIA BUNDLE X #4 MOUNT	2.00	EA	
H0511144006		058	SCREW, PAN HD CROSSED RECESSED, 4-40 X 3/8, SS	2.00	EA	
H0511183205		059	SCREW, PAN HD CROSSED RECESSED, 8-32 X 5/16, SS	1.00	EA	
H3001100400		060	WASHER, FLAT, #4, SS	1.00	EA	
H3031100800		061	WASHER, EXTERNAL TOOTH LOCK, #8, SS	1.00	EA	
503781	F	062	PIPE AND CLIP ASSEMBLY	1.00	EA	
900283	Α	063	O-RING, BUNA N, 70 DURO, 0.301 ID X 0.070 W X 0.441 OD	1.00	EA	
900691-27	G	064	TUBING, PVC, 1/2 ID X 5/8 OD X 1/16 THK	0.16	FT	
FEET 900957-05	C	065	ELBOW, BARBED, 1/2 X 1/2	1.00	EA	
900577	В	066	ADHESIVE, LOCTITE 222, THREADLOCKER, SMALL SCREW,	0.01	BT	
AS REQUIRED 900551-02	C	067	CABLE TIE, .87 INCH BUNDLE DIA, 3 7/8 LG	1.00	EA	

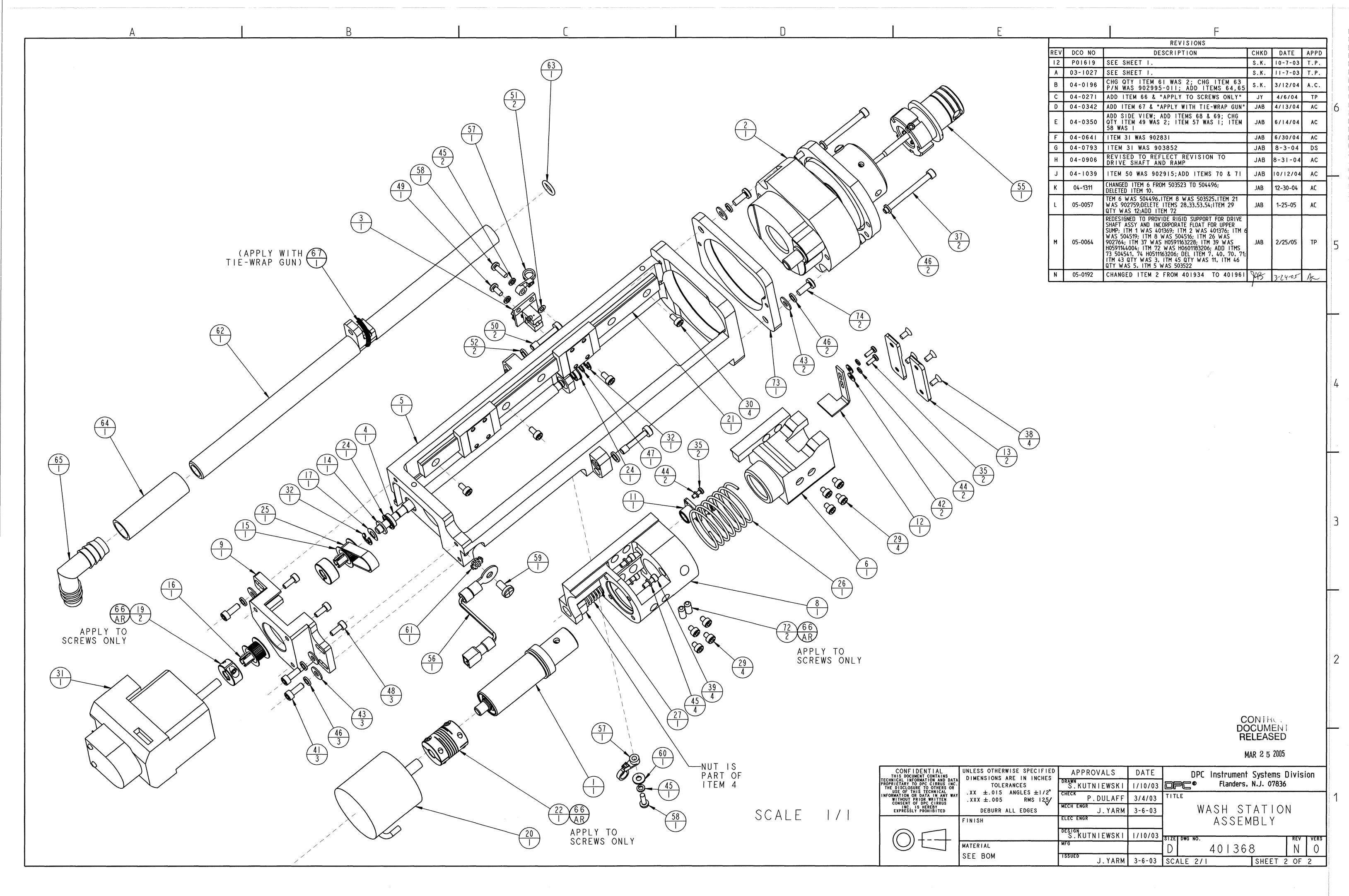
Bill of Materials

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Assembly 401368	Rev N	Assembly Description WASH STATION ASSEMBLY IMM 2500				
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
900725 FEET	В	068	TAPE, KAPTON	0.38	FT	
401794	C	069	CABLE ASSEMBLY, EXTENSION, HOME SENSOR	1.00	EA	
900782 AS REQUIRED	C	071	ADHESIVE, CYANOACRYLATE 910	0.01	BT	
H0601183206		072	SCREW, SET, CUP POINT HEX SOCKET, 8-32 X 3/8, SS	2.00	EA	
504541	Α	073	SPACER, SUMP	1.00	EA	
H0511163206		074	SCREW, PAN HD CROSSED RECESSED, 6-32 X 3/8, SS	2.00	EA	

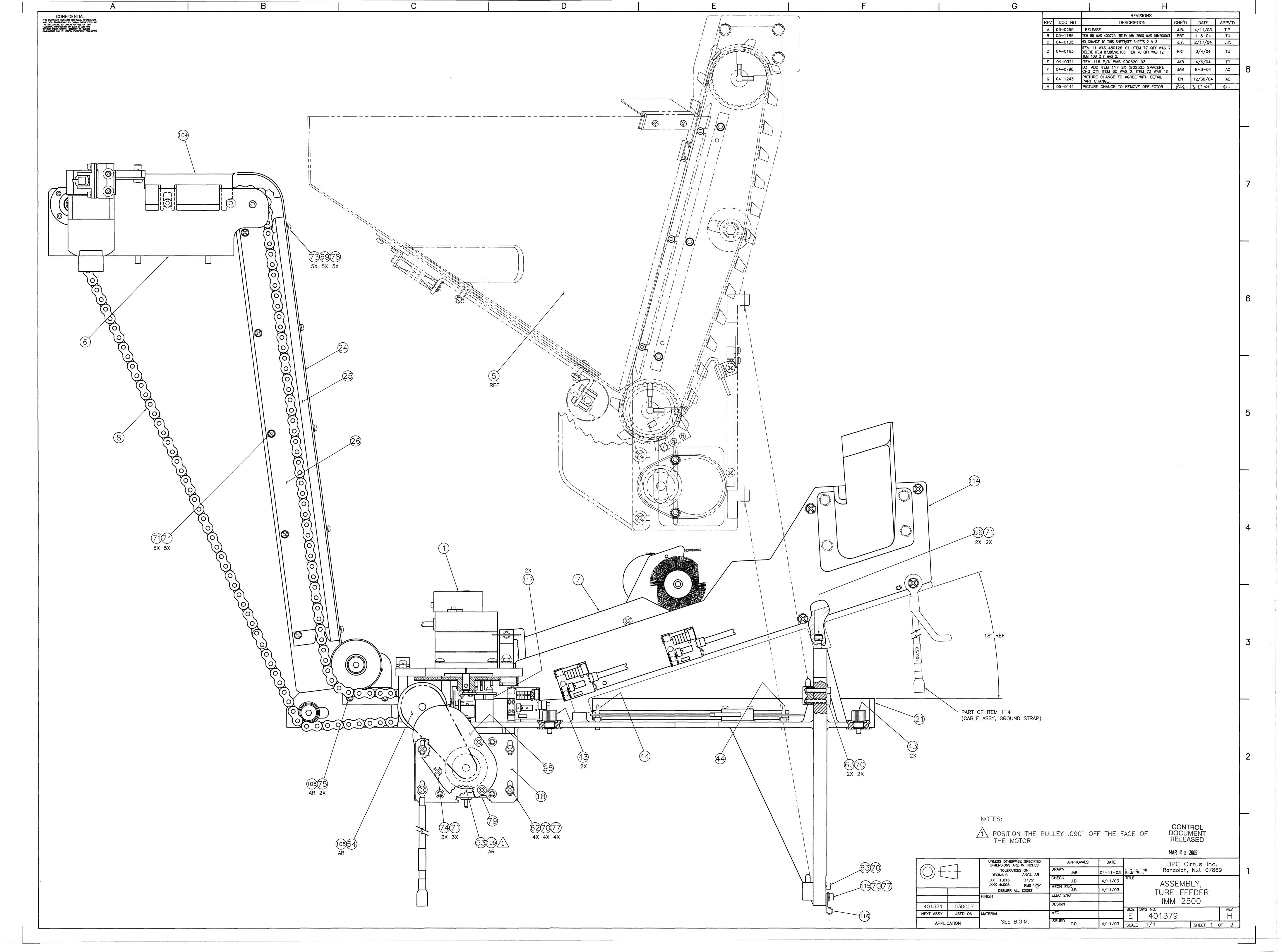


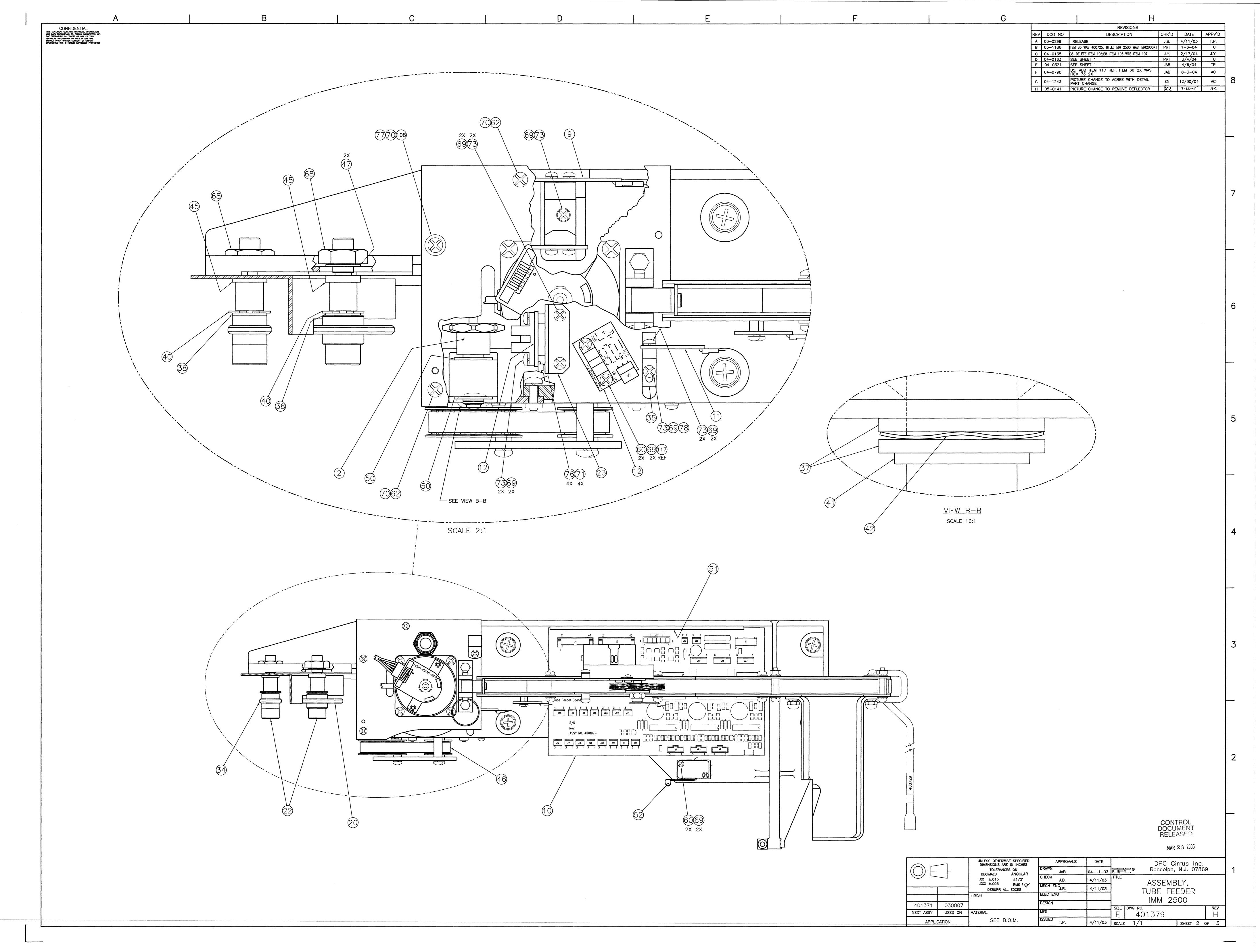


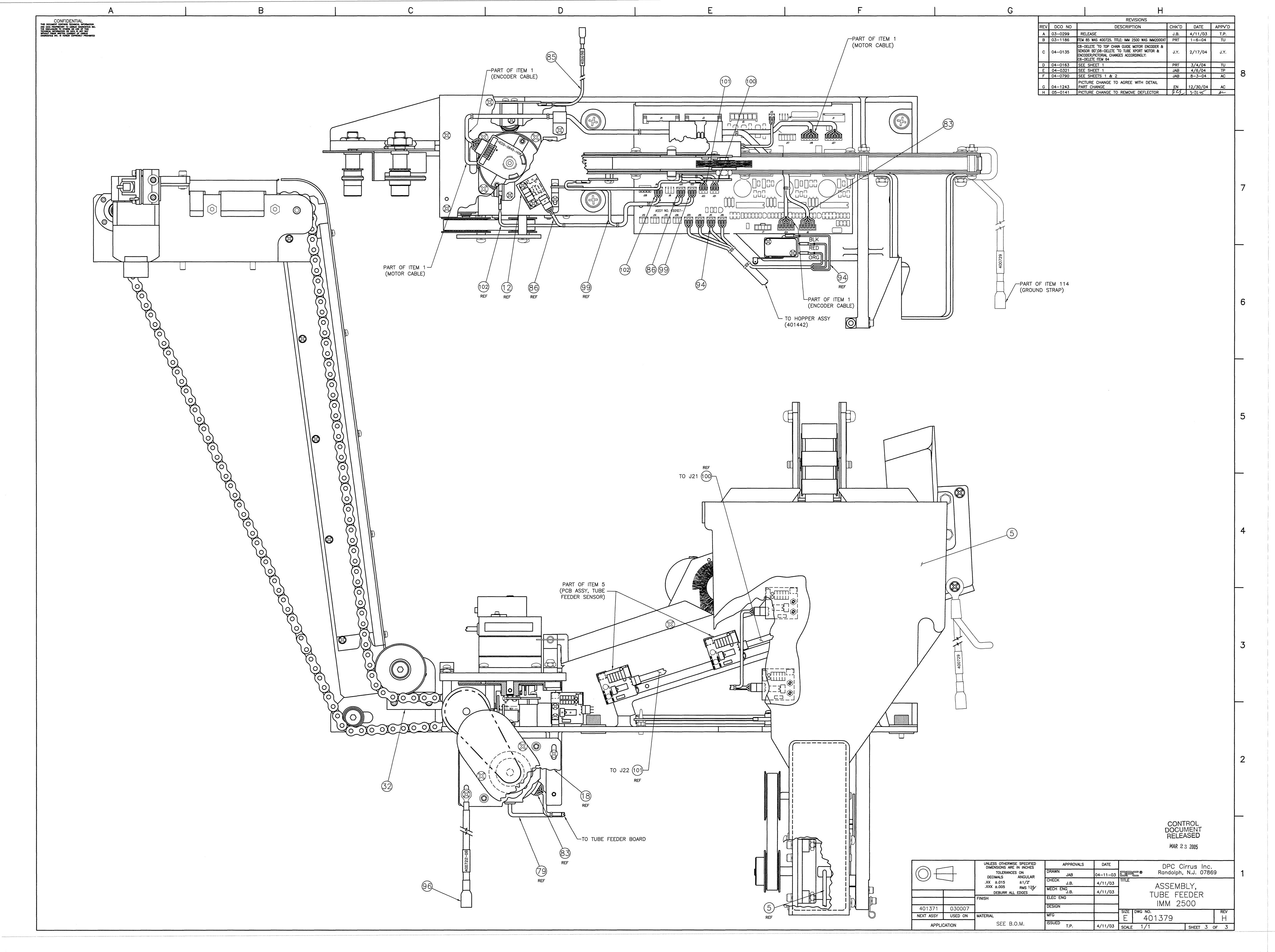
Assembly 401379	Rev H		ssembly Description UBE FEEDER ASSEMBLY IMM 2500			
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
400868	В	001	TUBE FEEDER SUBASSEMBLY	1.00	EA	
400515	Α	002	SHAFT ASSEMBLY, DRIVE CHAIN	1.00	EA	
401443	J	005	HOPPER ASSEMBLY, TUBE FEEDER	1.00	EA	
401372	Н	006	TOP CHAIN GUIDE ASSEMBLY, TUBE FEEDER IMM 2000	1.00	EA	
400592	Е	007	REJECT WHEEL ASSEMBLY, TUBE FEEDER	1.00	EA	
400626	В	008	CHAIN ASSEMBLY, TUBE FEEDER	1.00	EA	
400635	D1	009	BEAD SENSOR BOARD ASSEMBLY	1.00	EA	
450107	Л1	010	PCB ASSY, TUBE BEAD TRANSPORT	1.00	EA	
450301-01	В	011	PCB ASSY, TUBE FEEDER MODULATED SENSOR	1.00	EA	
450127-01	A2	012	PCB ASSY, HOME POSITION SENSOR	2.00	EA	
501103	В	018	MOUNT, MOTOR, TUBE FEEDER	1.00	EA	
501114	A	020	ROLLER, TUBE FEEDER, LARGE	1.00	EA	
501116	L	021	BASE, TUBE FEEDER, MACHINING	1.00	EA	
501117	Α	022	BOLT, TENSION, TUBE FEEDER	2.00	EA	
501118	Α	023	BRACKET, SENSOR, TUBE FEEDER	1.00	EA	
501122	В	024	GUIDE, TUBE, TUBE FEEDER	1.00	EA	
501123	Α	025	GUIDE, TOP CHAIN, TUBE FEEDER	1.00	EA	
501124	В	026	GUIDE, BOTTOM CHAIN, TUBE FEEDER	1.00	EA	
501273	В	032	GUIDE, LOWER TUBE, TUBE FEEDER	1.00	EA	
501289	A	034	ROLLER, TUBE FEEDER, SMALL	1.00	EA	
501351	C	035	MOUNT, SENSOR, TUBE FEEDER	1.00	EA	
900019	A	037	SPACER, SHAFT, 1/4 ID X 3/8 OD X 0.031 THK, S.S.	2.00	EA	
900059	В	038	SPACER, BEARING, 0.503 ID X 0.623 OD X 0.032 THK, S.S.	2.00	EA	
900063	D	040	RING, RETAINING, EXTERNAL, 1/2 SHAFT	2.00	EA	
900133-01	J	041	RING, RETAINING, EXTERNAL, 1/4 SHAFT	1.00	EA	
900152	A1	042	SPRING, BEARING PRELOAD, S.S., 0.265 ID X 0.367 OD	1.00	EA	
900378	C1	043	FASTENER, RETRACTABLE, PHILLIPS, 8-32, .283 LT	4.00	EA	
900388-04	Α	044	SUPPORT, STUDDED CIRCUIT BOARD, NYLON, 1/4 HIGH X 8-32 THRD	2.00	EA	

Assembly 401379	Rev H		ssembly Description UBE FEEDER ASSEMBLY IMM 2500			
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
900843-50	C1	045	WASHER	2.00	EA	_
901156	C	046	BELT, TIMING, 1/5 PITCH, 3/8 WIDE, 45 GROOVES	1.00	EA	
900032	Α	047	SPACER, SHAFT, 3/8 ID X 5/8 OD X 0.125 THK, S.S.	2.00	EA	
901350-17	D	050	BEARING, RDL, FLG, .2500 ID X .6250 OD X .1960 W, SHLD	2.00	EA	
901387	Α	051	GUIDE, CARD, INTERCHANGEABLE SNAP-IN	1.00	EA	
901398	В	052	SWITCH, MIRCO, ROLLER LEVER	1.00	EA	
901453-01	Α	053	PULLEY, TIMING BELT, 1/5 PITCH, 7/16 W, 12 GROOVES	1.00	EA	
901453-02	Α	054	PULLEY, TIMING BELT, 1/5 PITCH, 7/16 W, 24 GROOVES	1.00	EA	
H0511144010		060	SCREW, PAN HD CROSSED RECESSED, 4-40 X 5/8, SS	4.00	EA	
H0511163208		062	SCREW, PAN HD CROSSED RECESSED, 6-32 X 1/2, SS	6.00	EA	
H0591163212	-	063	SCREW, CAP, HEX SOCKET, 6-32 X 3/4, SS	3.00	EA	
H0591183210		066	SCREW, CAP, HEX SOCKET, 8-32 X 5/8, SS	2.00	EA	
H2071131600		068	NUT, HEX, NYLON INSERT LOCKNUT, 3/8, S.S	2.00	EA	
H3011100400		069	WASHER, SPLIT LOCK, #4, SS	17.00	EA	
H3011100600		070	WASHER, SPLIT LOCK, #6, SS	11.00	EA	
H3011100800		071	WASHER, SPLIT LOCK, #8, SS	14.00	EA	
H0511144006		073	SCREW, PAN HD CROSSED RECESSED, 4-40 X 3/8, SS	13.00	EA	
H0511183212		074	SCREW, PAN HD CROSSED RECESSED, 8-32 X 3/4, SS	8.00	EA	
H0591163208		075	SCREW, CAP, HEX SOCKET, 6-32 X 1/2, SS	2.00	EA	
H0511183207		076	SCREW, PAN HD CROSSED RECESSED, 8-32 X 7/16, SS	4.00	EA	
H3001100600		077	WASHER, FLAT, #6, SS	6.00	EA	
H3001100400		078	WASHER, FLAT, #4, SS	6.00	EA	
400511-07	Н	079	MOTOR ENCODER ASSEMBLY, TUBE FEEDER TUBE	1.00	EA	
400628-07	D2	083	TRANSPORT CABLE ASSEMBLY, ENCODER TUBE TRANSPORT	1.00	EA	
401698	В	085	CABLE ASSEMBLY, 1/2 BEAD	1.00	EA	
400646-13	G	086	CABLE ASSEMBLY, SENSOR	1.00	EA	
400658	C	094	CABLE ASSEMBLY, HOPPER CLOSE SWITCH	1.00	EA	
501581	В	095	GUARD, BELT DRIVE	1.00	EA	

Assembly 401379	Rev H		ssembly Description UBE FEEDER ASSEMBLY IMM 2500			
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
400722-08	E	096	CABLE ASSEMBLY, GROUND STRAP	1.00	EA	Ī
400646-14	G	099	CABLE ASSEMBLY, SENSOR	1.00	EA	
400646-15	G	100	CABLE ASSEMBLY, SENSOR	1.00	EA	
400646-16	G	101	CABLE ASSEMBLY, SENSOR	1.00	EA	
400646-17	G	102	CABLE ASSEMBLY, SENSOR	1.00	EA	
501755	D	104	GUARD, TUBE FEEDER U-CHANNEL	1.00	EA	
900577	В	105	ADHESIVE, LOCTITE 222, THREADLOCKER, SMALL SCREW,	0.00	BT	
AS REQUIRED H0511163210	Α	108	SCREW, PAN HD CROSSED RECESSED, 6-32 X 5/8, SS	1.00	EA	
401427	G	114	TUBE CHUTE ASSEMBLY	1.00	EA	
H0591163214	-	115	SCREW, CAP, HEX SOCKET, 6-32 X 7/8, SS	1.00	EA	
900620-04	D	116	CLAMP, CABLE, 1/4 DIA, 1/2 W, CELLULOSE	1.00	EA	
902323	A	117	SPACER	2.00	EA	







Assembly 401443	Rev L		ssembly Description OPPER ASSEMBLY, TUBE FEEDER			
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
400609	A	001	ALIGNMENT BAR ASSEMBLY	1.00	EA	
450301-03	C	002	PCB ASSY, TUBE FEEDER MODULATED SENSOR	2.00	EA	
450301-02	C	003	PCB ASSY, TUBE FEEDER MODULATED SENSOR	1.00	EA	
501094	D	004	SHAFT, 3.00, TUBE FEEDER	1.00	EA	
501095	Α	005	SHAFT, 2.31, TUBE FEEDER	1.00	EA	
501099	Α	006	BEARING, BELT TENSION, ELEVATOR, TUBE FEEDER	1.00	EA	
501100	\mathbf{A}_{\perp}	007	SHAFT, ELEVATOR BELT TENSIONER, TUBE FEEDER	1.00	EA	
501101	F	800	SUPPORT, TUBE FEEDER, LEFT HAND	1.00	EA	
501102	G	009	SUPPORT, TUBE FEEDER, RIGHT HAND	1.00	EA	
501104	Α	010	SUPPORT, BELT, TUBE FEEDER	1.00	EA	
501132	G	011	BELT, ELEVATOR	1.00	EA	
501134	В	012	ROD, CONNECTING, TUBE FEEDER	1.00	EA	
501138	C	014	SPRING GUIDE TUBE FEEDER	1.00	EA	
501143-01	E	015	GUIDE, TUBE, LEFT, TUBE FEEDER	1.00	EA	
501143-02	E	016	GUIDE, TUBE, RIGHT, TUBE FEEDER	1.00	EA	
501144	Α	017	PLATE, AGITATOR, TUBE FEEDER	1.00	EA	
503521	F	018	TUBE, VACUUM FORMED, HOPPER	1.00	EA	
501277	Α	019	BAR, SUPPORT, ELEVATOR, TUBE FEEDER	1.00	EA	
501375	D	020	PULLEY, ELEVATOR, TUBE FEEDER	2.00	EA	
501386	В	021	PULLEY, DRIVE, ELEVATOR BELT	1.00	EA	
900063	D	022	RING, RETAINING, EXTERNAL, 1/2 SHAFT	1.00	EA	
900061	Α	023	WASHER, THRUST, $1/2$ ID X $15/16$ OD X 0.062 THK, S.S.	1.00	EA	
900133-01	J	024	RING, RETAINING, EXTERNAL, 1/4 SHAFT	10.00	EA	
900152	A 1	025	SPRING, BEARING PRELOAD, S.S., 0.265 ID X 0.367 OD	4.00	EA	
H0601183203		026	SCREW, SET, CUP POINT HEX SOCKET, 8-32 X 3/16, SS	10.00	EA	
H2051163200	-	027	NUT, HEX CAP (ACORN), 6-32, SS	6.00	EA	
900019	Α	028	SPACER, SHAFT, 1/4 ID X 3/8 OD X 0.031 THK, S.S.	6.00	EA	
400651	\mathbf{C}	029	CABLE ASSEMBLY, AC MOTOR/SWITCH TUBE SORTER	1.00	EA	

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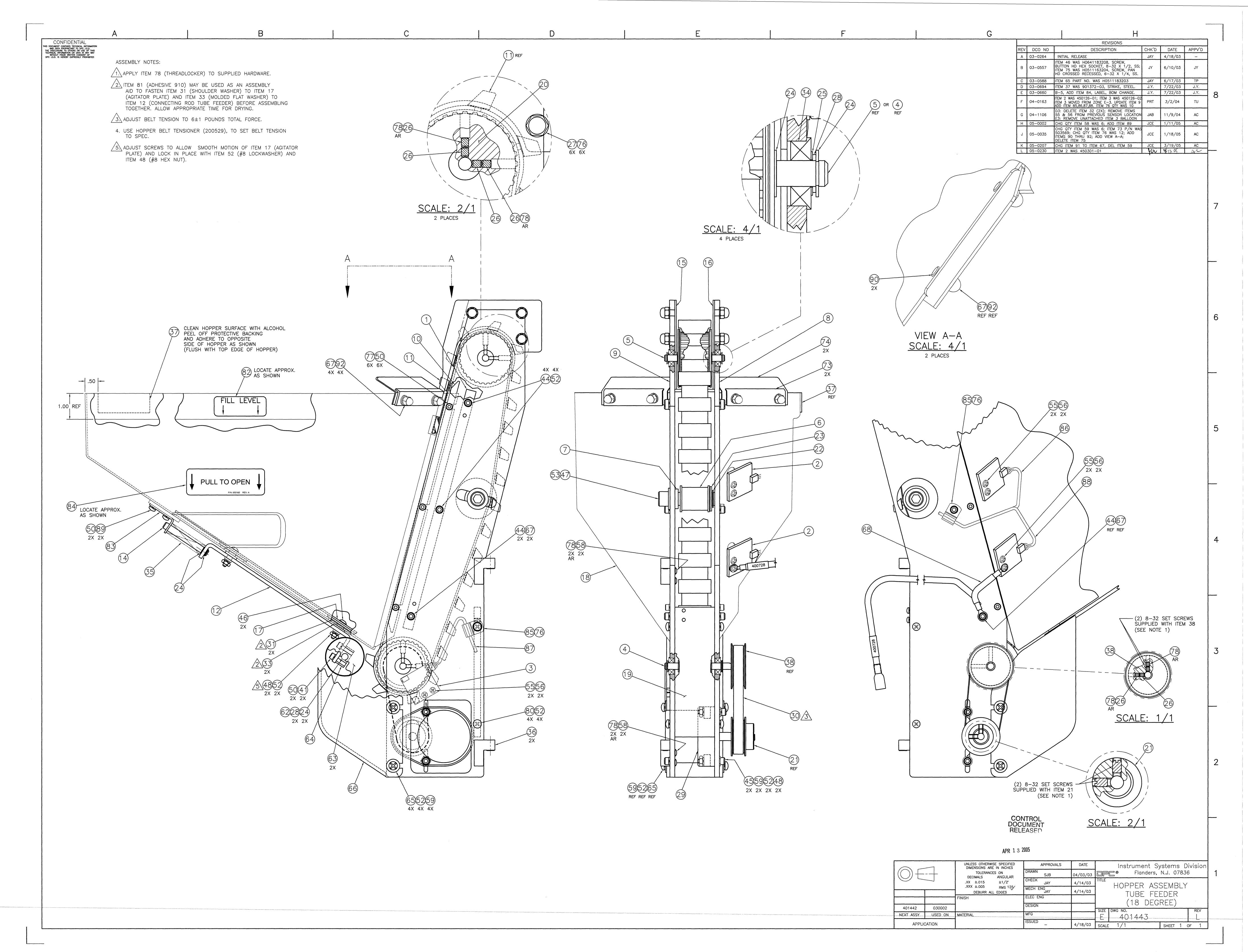
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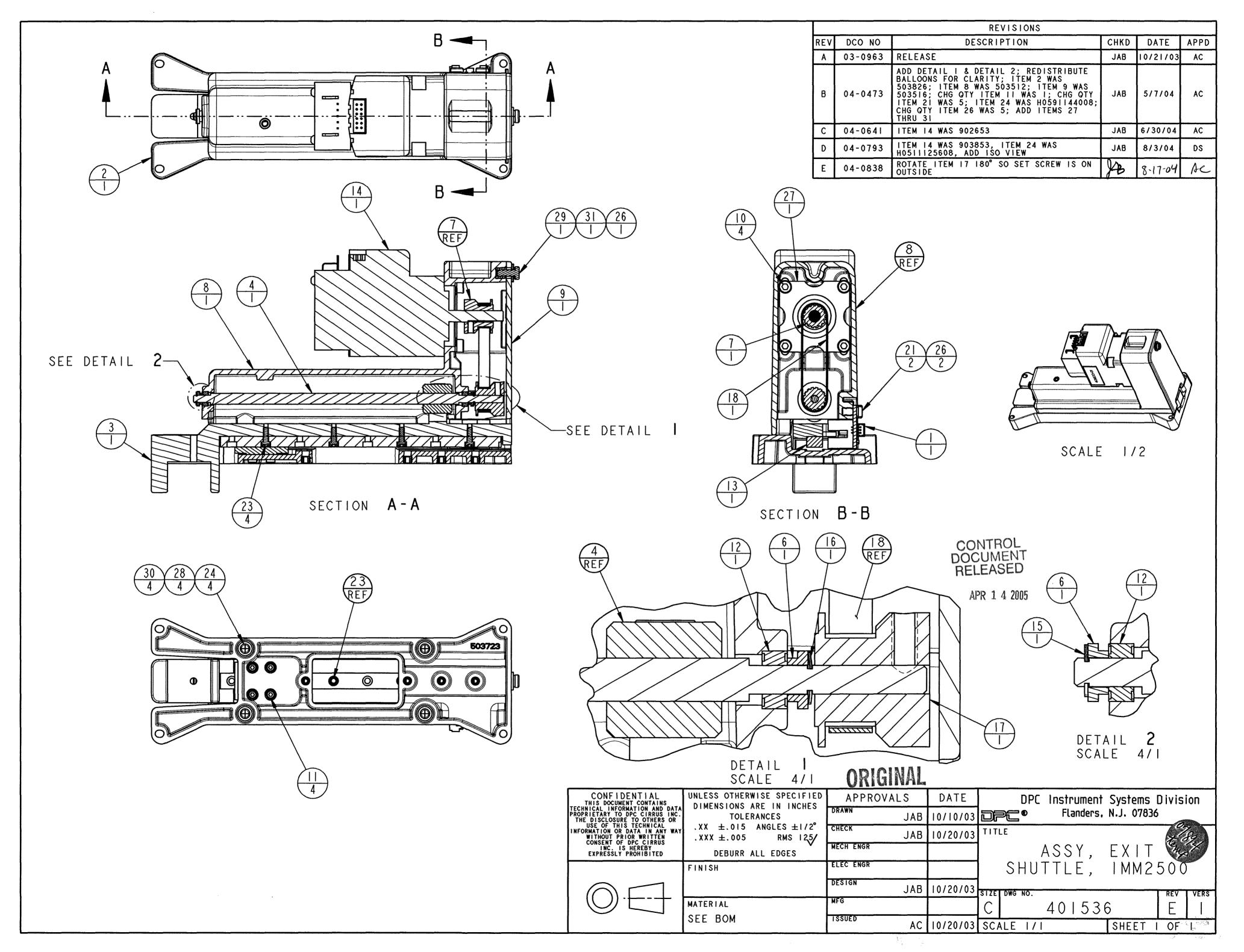
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	Component	Rev	Item	Component Description	Qty Per Assy	U/M	
	901572	Α	030	BELT, TIMING, 1/5 PITCH, 3/8 WIDE, 49 GROOVE	1.00	EA	
	501455	Α	031	WASHER, SHOULDER	2.00	EA	
	901349-102	C	033	WASHER, FLAT, MOLDED	2.00	EA	
	901350-17	D	034	BEARING, RDL, FLG, .2500 ID X .6250 OD X .1960 W, SHLD	4.00	EA	
	901698	Α	035	SPRING, COMPRESSION, .035 WD X .480 OD X 2.0 FL, S.S.	1.00	EA	
	901355	Α	036	HINGE, LIFT-OFF, OFFSET MINI	2.00	EA	
	901372-06	C	037	STRIKE, STEEL, ADHESIVE MOUNT	1.00	EA	
	901453-02	Α	038	PULLEY, TIMING BELT, 1/5 PITCH, 7/16 W, 24 GROOVES	1.00	EA	
	H0591163208		041	SCREW, CAP, HEX SOCKET, 6-32 X 1/2, SS	2.00	EA	
	Н0591183210		044	SCREW, CAP, HEX SOCKET, 8-32 X 5/8, SS	6.00	EA	
	H0591183114		045	SCREW, CAP, HEX SOCKET, 8-32 X 7/8, SS	2.00	EA	
	H0511183213		046	SCREW, PAN HD CROSSED RECESSED, 8-32 X 13/16, SS	2.00	EA	
	H0591131614	-	047	SCREW, CAP, HEX SOCKET, 3/8-16 X 7/8, SS	1.00	EA	
	H2001183200		048	NUT, HEX, 8-32, SS	4.00	EA	
	Н3011100600		050	WASHER, SPLIT LOCK, #6, SS	10.00	EA	
	H3011100800		052	WASHER, SPLIT LOCK, #8, SS	16.00	EA	
	H3001103800	-	053	WASHER, FLAT, 3/8, SS	1.00	EA	
	H0511144006		055	SCREW, PAN HD CROSSED RECESSED, 4-40 X 3/8, SS	6.00	EA	
	H3011100400		056	WASHER, SPLIT LOCK, #4, SS	6.00	EA	
	H0511163207		058	SCREW, PAN HD CROSSED RECESSED, 6-32 X 7/16, SS	4.00	EA	
	H3001100800		059	WASHER, FLAT, #8, SS	6.00	EA	
	501442	Α	062	ROLLER, SHAFT AGITATOR	1.00	EA	
	501443	C1	063	ROLLER, HOPPER AGITATOR	2.00	EA	
	501444	В	064	MOUNT, AGITATOR SHAFT	1.00	EA	
	H0511183206		065	SCREW, PAN HD CROSSED RECESSED, 8-32 X 3/8, SS	4.00	EA	
	501580	С	066	GUARD, HOPPER AGITATOR	1.00	EA	
	H3021100800	-	067	WASHER, INTERNAL TOOTH LOCK, #8, SS	6.00	EA	
•	400728	Α	068	CABLE ASSEMBLY, GROUND STRAP, DUAL	1.00	EA	

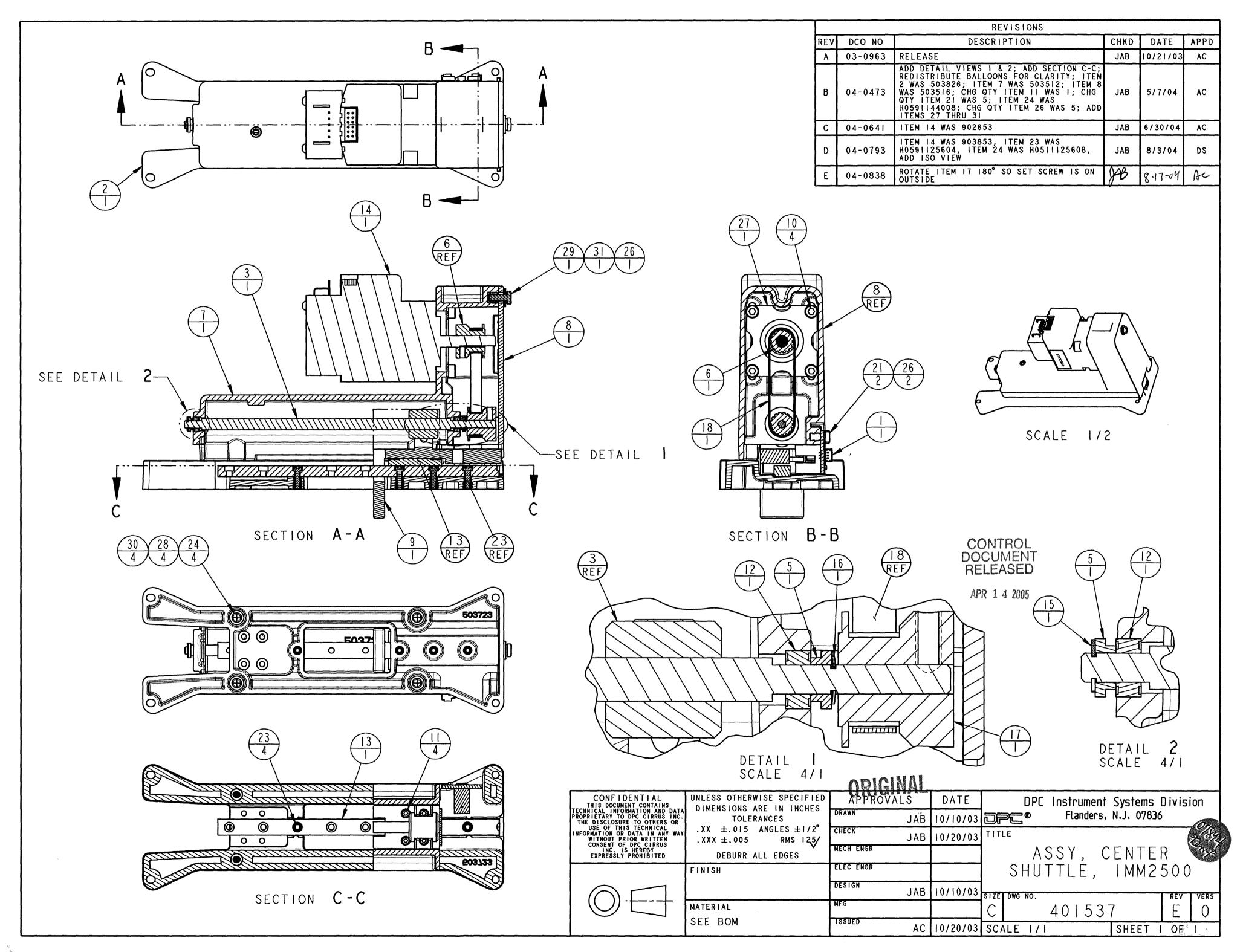
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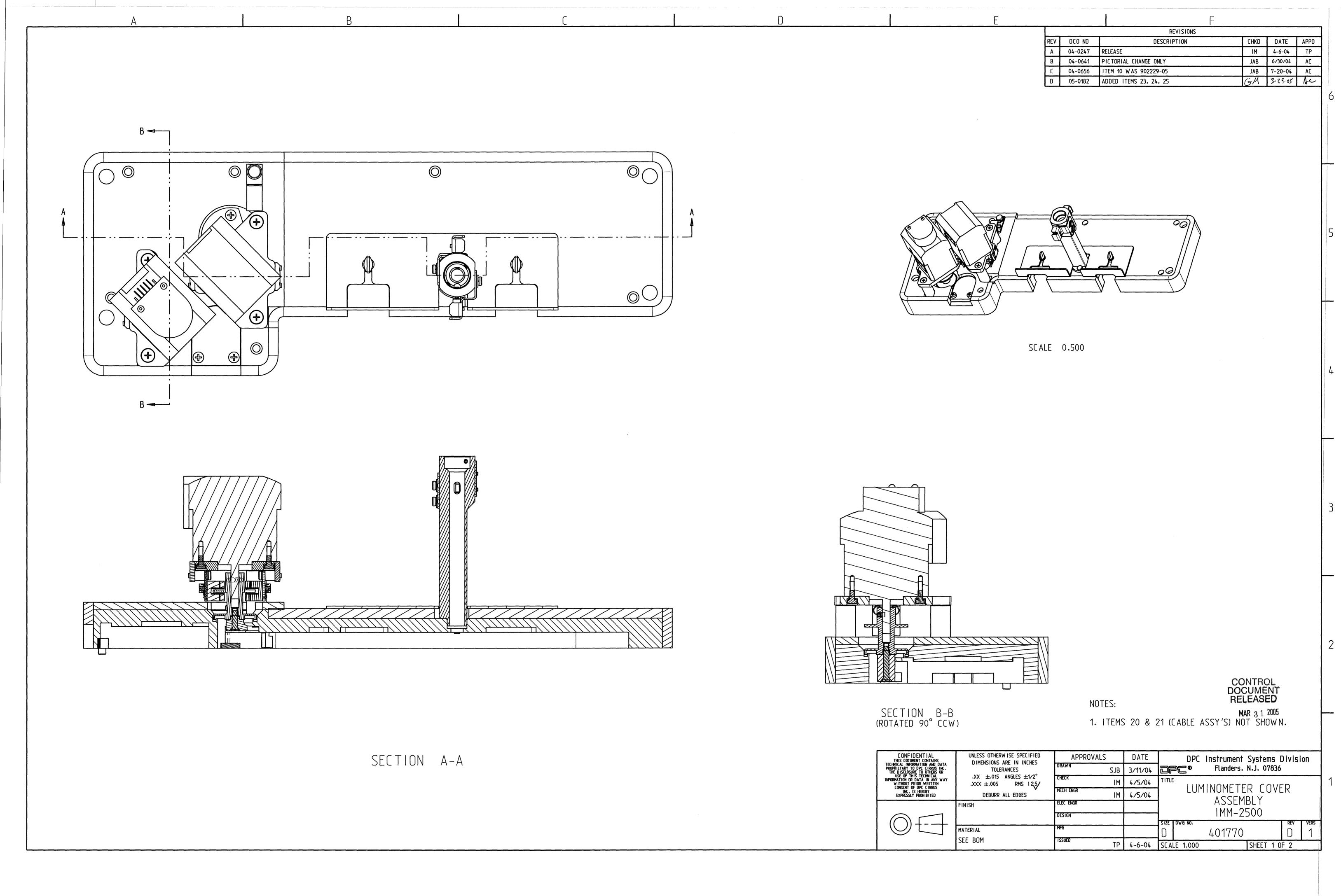
Assembly 401443	Rev L		ssembly Description OPPER ASSEMBLY, TUBE FEEDER			
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
501633	С	073	MOUNT, RETAINING, TUBE HOPPER	2.00	EA	_
501634	D	074	RETAINER, TUBE HOPPER	2.00	EA	
H3001100600		076	WASHER, FLAT, #6, SS	8.00	EA	
Н0591163212	-	077	SCREW, CAP, HEX SOCKET, 6-32 X 3/4, SS	6.00	EA	
900577	В	078	ADHESIVE, LOCTITE 222, THREADLOCKER, SMALL SCREW,	0.00	BT	
AS REQUIRED H0511183210		080	SCREW, PAN HD CROSSED RECESSED, 8-32 X 5/8, SS	4.00	EA -	
900782	С	081	ADHESIVE, CYANOACRYLATE 910	0.01	вт	
AS REQUIRED 650161	A	082	LABEL, FILL LEVEL	1.00	EA	
503570	A	083	ANGLE, HOPPER	1.00	EA	
650165	A	084	LABEL, PULL TO OPEN, HOPPER ASSEMBLY	1.00	EA	
900620-04	D	085	CLAMP, CABLE, 1/4 DIA, 1/2 W, CELLULOSE	2.00	EA	
400646-03	G	086	CABLE ASSEMBLY, SENSOR	1.00	EA	
400646-11	G	087	CABLE ASSEMBLY, SENSOR	1.00	EA	
400646-12	G	088	CABLE ASSEMBLY, SENSOR	1.00	EA	
H0511163204	-	089	SCREW, PAN HD CROSSED RECESSED, 6-32 X 1/4, SS	2.00	EA	
904050	A	090	STUD, 8-32 X 3/8	4.00	EA	
H2051183200	-	092	NUT, HEX CAP (ACORN), 3/8, SS	4.00	EA	







Assembly 401770	Rev D		ssembly Description UMINOMETER COVER ASSEMBLY			
Component	Rev	Item	Component Description	Qty Per Assy	U/M	
401220	F	001	MOTOR SUBASSEMBLY, TUBE SHUTTLE	1.00	EA	
401333	E	002	TUBE SHUTTLE EXIT MOTOR SUBASSEMBLY	1.00	EA	
401456	D	003	SUPPORT ASSEMBLY, SUBSTRATE PROBE	1.00	EA	
401471	В	004	COVER PINNING ASSEMBLY	1.00	EA	
502709-01	Α	005	POST	4.00	EA	
502739	Α	006	LID, SENSOR COVER	1.00	EA	
503228	Α	007	GUIDE, TUBE TRANSFER	1.00	EA	
503461	Α	008	LID, EXIT, LUMINOMETER	1.00	EA	
901997-1309	D	009	SPACER, ROUND, .3125 OD X .166 ID X .6875 LG	1.00	EA	
903863	Α	010	CLAMP, CABLE, 1/2 DIA, 3/8 W	1.00	EA	
902737-01	C	011	SCREW, CAPTIVE, 8-32 X 1/2 LG	3.00	EA	
H0511163208		012	SCREW, PAN HD CROSSED RECESSED, 6-32 X 1/2, SS	2.00	EA	
H0511183218		013	SCREW, PAN HD CROSSED RECESSED, 8-32 X 1 1/8, SS	1.00	EA	
H0571144004	-	014	SCREW, FLAT HD CROSSED RECESSED, 4-40 X 1/4, SS	2.00	EA	
H0571183208		015	SCREW, FLAT HD CROSSED RECESSED, 8-32 X 1/2, SS	8.00	EA	
H3001100800		016	WASHER, FLAT, #8, SS	1.00	EA	
H3011100600		017	WASHER, SPLIT LOCK, #6, SS	2.00	EA	
H3011100800		018	WASHER, SPLIT LOCK, #8, SS	1.00	EA	
504307-01	В	019	KIT, INSULATION, LUMINOMETER COVER	1.00	EA	
401670	C	020	CABLE ASSEMBLY, LUMINOMETER SHUTTLE/EXIT	1.00	EA	
401678	C	021	CABLE ASSEMBLY, LUMINOMETER SHUTTLE/PROBE	1.00	EA	
500292-03	D	022	PAD, LIGHT SEAL	1.00	EA	
904094	A	023	SPACER, ROUND, .375 OD X .171 ID X .250 THK, NYLON	2.00	EA	
504560	Α	024	GUARD, WASH STATION IMM 2500	1.00	EA	
901063-04	Α	025	SCREW, THUMB, SHOULDER TYPE STEEL FLAT POINT 8-31 X 1/2 LG	2.00	EA	



Appendix A: Definition of Terms

This section contains an explanation of terms relevant to servicing the IMMULITE 2000/2500.

Back-Up Process – The back-up process occurs when logging off the IMMULITE 2000/2500 software. During this process, important files are copied from one directory to another. In addition, the previous copy of the maindata.mdb file in the back-up directory is re-named by date and time and the file extension is changed to .xdb. The system keeps only five of these .xdb files in the back-up folder by deleting the oldest file during the back-up process.

The path of the back-up directory is affected by the hard drive configuration. If the system is in Dupli-Disk mode, the back-up path is to the C:\ drive because there is no D:\ hard drive. If the system is not in Dupli-Disk mode but in a master/slave configuration, the back-up path should be to the D:\ drive in case the C:\ drive physically fails. Selecting the "Mirror Board Installed" box in the IMMULITE 2000/2500 software under DPC Configurations, configures the path of the back-up.

During the back-up process, all files in the "C:\IMMULITE 2000\Databases" folder are copied to the "Back-Up Files" folder in the either the C:\ or D:\ drive. The folders including their content (C:\IMMULITE 2000\DiagPrograms and C:\IMMULITE2000\DiagConfig) are copied to the same "Back-Up Files"

Dupli-Disk – Dupli-Disk is a hard drive configuration, which uses a PCB to act as a Host hard drive and then write all information to two hard drives. This creates a duplicate hard drive in case one of the two hard drives physically fails. The motherboard only sees one hard drive, which is the Dupli-Disk PCB. The Dupli-Disk PCB reads from the Primary hard drive and writes to both the Primary and the mirror hard drive.

Since both hard drives are identical, if there is a problem with Windows NT, incorrect drivers are loaded or some other software or database problem develops, the problem will exist on both the primary and mirror hard drive. The effectiveness of using the Dupli-Disk PCB is seen when one of the hard drives develops a physical problem preventing it from operating correctly. The Dupli-Disk PCB will detect this and alarm to report the problem, however the system will continue to operate, as the

Dupli-Disk PCB will use the other hard drive. The problem can be repaired at a later arranged time resulting in minimum down time.

Ghosting – Ghosting is the process of installing software by copying an image from a CD to one hard drive. All information previously on the hard drive will be lost as the image is placed on the hard drive. There are ghost CDs for the different user side motherboards and one Control-side CD. There are different User CDs because of the vast differences among the motherboards and differences in the associated drivers.

The Ghosting process is used primarily to fix a Windows NT problem, which prevents the hard drive from booting up properly. It can also be used to clean a hard drive by overwriting the old information with the new image.

In addition, each ghost CD (User or Control) installs a version of IMMULITE 2000/2500 Software. When ghosting, the IMMULITE 2000/2500 Software is only placed on the one side so care must be taken after ghosting to ensure both User and Control are running the same version of the software.

The ghosting software does not install files that are unique to the specific instrument. For example the maindata.mdb, errorlog.mdb, motorfig.mdb and position.iml files must be restored.

Promise Card – Promise Card, similar in function to the Dupli-Disk PCB, is a hard drive configuration, which uses a PCB to act as a Host hard drive and then will write all information to two hard drives. This creates a duplicate hard drive in case one of the two hard drives physically fails. The motherboard only sees one hard drive, which is the Promise Card PCB. The Promise Card PCB reads from the Primary hard drive (IDE 1) and writes to both the Primary and the Mirror hard drive (IDE 2). Due to the rapid size increase of the Hard Disk Drives, the Promise Card, with a much faster data transfer rate will copy more quickly (typically within 20 minutes) from one drive to another in the event hard drive replacement is necessary.

Appendix B: Extended System Testing

Tube Feeder Sensors

This section contains an explanation of the configuration of the optical sensors in the Tube Feeder assembly. It explains how to tell the difference between the two types of the sensors and the adjustment process for each one.

There are six optical sensors in the Tube Feeder module – the hopper low and full, tube at the indexer, elevator motion, and the queue low and high in the chute – that are very similar to each other. The part numbers are as follows:

- 450126-01 Hopper low and full sensors and Tube at the indexer sensor
- o 450126-02 Elevator motion sensor
- 450126-03 Tube queue low and high sensors

Hopper Low Sensor – This sensor detects tubes in the bottom of the hopper.

Hopper Full Sensor – This sensor detects tubes in the top of the hopper.

Tube at Indexer Sensor – This sensor detects the presence of a tube in the indexer at the queue position.

Elevator Motion Sensor – This sensor detects the motion of the elevator belt.

Tube Queue Low Sensor – This sensor detects the absence of tubes in the lower part of the queue chute and then sends a signal, which turns on the elevator motor to fill the queue chute.

Tube Queue High Sensor – This sensor detects tubes in the upper part of the queue chute and then sends a signal, which turns off the elevator motor and prevents the queue chute from over filling.

Adjust the potentiometer (R8) for proper operation of the sensor when replacing one of these sensors. There have been two different circuits used on these sensors PCBs and the first step when adjusting a sensor is to determine the type of circuit.

Type	PCB Assembly Revision	Instrument Serial Number
I	A - E	B0001 - C0346
II	F-G	C0347 and Up

After determining what type of sensor the PCB assembly is the next step when configuring the sensor is to measure voltages and adjust accordingly. The directions listed below detail the steps involved to configure each of the six sensors for each type of sensor.

NOTE: Each type of sensor can be used in any instrument, so be sure to check the PCB assembly revision before adjusting. If the sensor was replaced previously, the replaced sensor might be a different type then indicated by the instrument serial number.

Type I

Hopper Low Sensor

With the hopper empty, measure the voltage on pin 2 of the comparator (U1) and record this voltage as V1. While measuring the voltage on pin 2, use tubes to block the sensor and record this voltage as V2. Add V1 and V2 and divide the sum by two. Record this number as V3. While measuring the voltage on pin 3, turn the potentiometer (R8) until the voltage is the same as V3.

Hopper Full Sensor

With the hopper empty, measure the voltage on pin 2 of the comparator (U1) and record this voltage as V1. While measuring the voltage on pin 2, use tubes to block the sensor and record this voltage as V2. Add V1 and V2 and divide the sum by two. Record this number as V3. While measuring the voltage on pin 3, turn the potentiometer (R8) until the voltage is the same as V3.

Tube at Indexer Sensor

Without a tube in the indexer and the indexer at the queue position, measure the voltage on pin 2 of the comparator (U1) and record this voltage as V1. While measuring the voltage on pin 2, place a tube in the indexer at the queue position and record this voltage as V2. Add V1 and V2 and divide the sum by two. Record this number as V3. While measuring the voltage on pin 3, turn the potentiometer (R8) until the voltage is the same as V3.

Elevator Motion Sensor

While measuring the voltage on pin 2 of the comparator (U1), manually move the elevator belt to determine the lowest voltage and record this voltage as V1. Then manually move the belt again to determine the highest voltage on pin 2 and record this as V2. Add V1 and V2 and divide the sum by two. Record this number as V3. While measuring the voltage on pin 3, turn the potentiometer (R8) until the voltage is the same as V3.

Tube Queue Low Sensor

With the queue chute empty, measure the voltage on pin 2 of the comparator (U1) and record this voltage as V1. Place two tubes next to each other in the chute and move and hold the tubes so they meet in front of the sensor. While measuring pin 2, determine the lowest voltage when moving the tubes and record this as V2. It is important to properly do this to achieve the worst case scenario, so the sensor will trigger even when the tubes are only slightly blocking the sensor. Add V1 and V2 and divide the sum by two. Record this number as V3. While measuring the voltage on pin 3, turn the potentiometer (R8) until the voltage is the same as V3.

Tube Queue High Sensor

With the queue chute empty, measure the voltage on pin 2 of the comparator (U1) and record this voltage as V1. Place two tubes next to each other in the chute and move and hold the tubes so they meet in front of the sensor. While measuring pin 2, determine the lowest voltage when moving the tubes and record this as V2. It is important to properly do this to achieve the worst case scenario, so the sensor will trigger even when the tubes are only slightly blocking the sensor. Add V1 and V2 and divide the sum by two. Record this number as V3. While measuring the voltage on pin 3, turn the potentiometer (R8) until the voltage is the same as V3.

Type II

Hopper Low Sensor

With the hopper empty, turn the potentiometer (R8) so Pin 2 of the comparator (U1) reads 1.0 V. Block the sensor with tubes and measure the value of Pin 2, voltage should now be greater than 2.5 V; if not the sensor is defective.

Hopper Full Sensor

With the hopper empty, turn the potentiometer (R8) so Pin 2 of the comparator (U1) reads 1.0 V. Block the sensor with tubes and measure the value of Pin 2, voltage should now be greater then 2.5 V; if not the sensor is defective.

Tube at Indexer Sensor

Remove all tubes from the queue chute and the indexer and then with the indexer at the queue position turn the potentiometer (R8) so pin 2 of the comparator (U1) reads 1.0 V. Place a tube in the queue chute so it slides down into the indexer and then measure pin 2. The voltage should now be greater than 2.5 V if not the sensor is defective.

Elevator Motion Sensor

While measuring the voltage of Pin 2 of the comparator (U1) manually move the elevator belt until the lowest voltage is found. Then turn the potentiometer (R8) so the voltage now reads 2.0 V. Manually move the elevator belt while measuring the pin 2 voltage until the highest voltage is reached. This voltage must be over 2.5 V; if not the sensor is defective.

Tube Queue Low Sensor

With the queue chute empty, turn the potentiometer (R8) so Pin 2 of the comparator (U1) reads 1.0 V. Fill the queue chute with tubes and then move the tubes while measuring Pin 2 and determine the lowest reading. The lowest reading is when two tubes meet in front of the sensor. It is important to properly do this to achieve the worst case scenario, so the sensor will trigger even when the tubes are only slightly blocking the sensor. This lowest value has to be above 2.5 V; if not the sensor is defective.

Tube Queue High Sensor

With the queue chute empty, turn the potentiometer (R8) so Pin 2 of the comparator (U1) reads 1.0 V. Fill the queue chute with tubes and then move the tubes while measuring Pin 2 and determine the lowest reading. The lowest reading is when two tubes meet in front of the sensor. It is important to properly do this to achieve the worst-case scenario, so the sensor will trigger even when the tubes are only slightly blocking the sensor. This lowest value has to be above 2.5 V; if not the sensor is defective.

Beginning with Serial Number I3447 and **ALL** IMMULITE 2500, we began using the Modulated Sensors. The following are the Calibration requirements for them.

Calibration Procedure for Modulated Sensors:

Modulated Sensor PCB Part # 450301-01:

Hopper Low Level, Hopper Full, Queue Low, Queue Full and Indexer Home Sensor. Use J3 pin one for (-) ground test point (the pin closest to the POT. R8) and J3 pin two for (+) positive test point.

Sensor	Pot R8	AC Voltage Reading at J3			
		Empty	With Tubes		
Hopper Upper and Lower	Set to full CW	NA	> 25mv		
Tube Indexer NOTE: Ensure the indexer is properly aligned at the tube queue position prior to the sensor adjustment.	Set R8 full CW and back off ¼ turn. Adjust R8 until the Empty spec is met.	< 9mv	> 35mv		
Queue Full and Low Sensors	With the Reject Wheel Motor assembly in place, adjust R8 until the Empty spec is met.	< 10mv	> 30mv		

Modulated Sensor PCB Part # 450301-02

Hopper Elevator Belt Sensor. Use J3 pin one for (-) ground test point (the pin closest to the POT. R8) and J3 pin two for (+) positive test point.

Sensor	Pot R8	AC Voltage	Reading at J3	
		No Teeth at sensor	Tooth at Sensor	
Elevator Belt Sensor	With the teeth of the belt between the sensor (not in front), adjust the sensor until the "no teeth" spec is met.	< 9mv	> 75mv	

Testing I/O
Panel using
Hyper-

The following test will determine the functionality of the Com Ports on the I/O Panel.

Terminal or Rocket Port-Rocket Modem

<u>Note</u>: You will need a NULL Modem Cable to perform either of these test.

To Test I/O Panel using the HyperTerminal Application

- 1. Go to Start -> Programs -> Accessories -> Hyperterminal -> Hyperterminal.
- 2. Then ENTER.
- 3. For NAME type in a name (For example **Rita**). Then **OK**
- **4.** CONNECT USING whatever COM Port you are testing. For example **COM 3**.
- 5. Then OK.
- **6.** In the next screen enter the following information:
 - o Bits per second: 9600
 - o Data Bits: 8
 - o Parity: **NONE**
 - o Stop Bits: 1
 - Flow Control: NONE
- 7. Select OK.
- **8.** This will initialize that particular COM Port for testing.
- **9.** Repeat steps 1-7 for another Com Port.
- **10.** Then try to communicate (type in information) between the two screens.

To Test I/O Panel using the Rocketport Rocketmodem Card:

- **1.** Go to Start -> Programs -> Comtrol RocketPortRocketModem -> Test Terminal.
- 2. Highlight PORT then click OPEN PORT.
- **3.** Choose COM3 (this will be to test the Modem port). NOTE: Make this screen smaller to allow a second port to open.
- **4.** Highlight PORT then click OPEN PORT.
- **5.** Choose COM8 (this will be to test the LIS port). NOTE: Adjust this screen size to enable both screens to be seen.
- **6.** Highlight PORT then SEND TEST DATA. You will see the Alphabet scrolling across the screen. The blinking square cursor will be the sender port.

Appendix C: User and Control Motherboards

User-Side Motherboards

IMPORTANT: Keep in mind that some of these instrument have been upgraded to different chassis, therefore you need to visually inspect the electronic chassis to confirm the Motherboard in use.

AT User Motherboard – B0001 to D0403

ATX User Seattle Motherboard – D0404 to F1580, F1585, and F1615

ATX User 815 Motherboard – F1581, F1582, F1583, F1584, F1616 – H2642

ATX User Pro-X Style Motherboard – H2643 – J3730

ATX User Pro-X 1750 Motherboard – J3731 and Higher

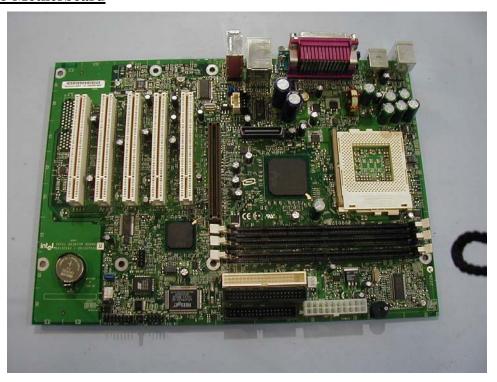
AT User Motherboard



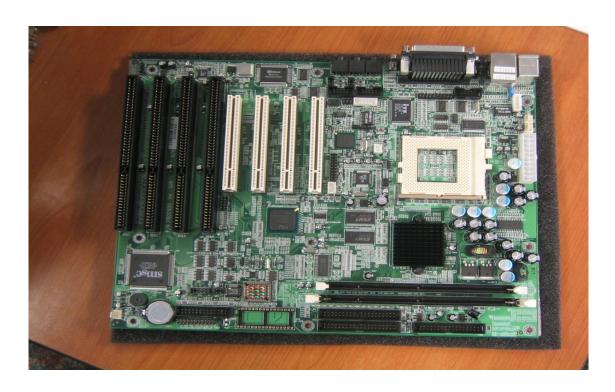
ATX User Seattle Motherboard



ATX User 815 Motherboard



PRO X User 1630 Motherboard



PRO X User 1750 Motherboard



Control-Side Motherboards

IMPORTANT: Keep in mind that some of these instrument have been upgraded to different chassis, therefore you need to visually inspect the electronic chassis to confirm the Motherboard in use.

Control AT Motherboard – B0001 to D0403

Teknor Single Board Computer – D0404 to F1540

Aaeon Single Board Computer – F1541 to G2039

Pro-X Single Board Computer – G2040 and higher

Control AT Motherboard



Teknor Control Motherboard



Aaeon Control Motherboard



Pro-X Control Motherboard



Appendix D: Decontamination Recommendations and Procedures

Decontamination of IMMULITE 2000/2500

The best way to completely decontaminate the IMMULITE 2000/2500 is to utilize NaOH (Sodium Hydroxide). The concentration for NaOH is 0.1 M.

To achieve this concentration you must mix 4 grams of NaOH per 1000 milliliters of Distilled Water.

Using NaOH will enable you to decontaminate the entire system, including the Clot Transducer and Substrate System (Bottle, Tubing, Pump, and Probe).

If NaOH is unavailable, then Probe Wash (SEE NOTES BELOW) can be used.

Notes:

- When using Probe Wash you **cannot** decontaminate the Substrate System or Clot Transducer (if Probe Wash is used the surface of the transducer will be damaged).
- 70% or Greater Alcohol can only be used to clean out the Water and Probe Wash Bottles. Alcohol **cannot** be used to decontaminate the IMMULITE 2000 because it will damage the Ceramic Valves and the sample and reagent manifold blocks, and leak around the seals of the Dilutors.

Decontaminating Substrate Section

Notes:

- When performing these procedures, place the Substrate Probe in the Reagent Wash Well. This will avoid flooding the Tube Processor.
- DO NOT USE Probe Wash to decontaminate the Substrate System.
 - 1. Pump the Substrate out of the Substrate Probe.
 - 2. Fill an empty Substrate Bottle half way to full with 0.1M NaOH.
 - **3.** Prime the Substrate Line until the 0.1 NaOH dispenses through the Substrate Probe; continue priming for a few minutes.
 - **4.** After priming for a few minutes, let the 0.1 NaOH sit in the Substrate System for 20 minutes.
 - **5.** After the 20 minutes, pump the Substrate Bottle dry.
 - **6.** Once the Substrate Bottle is empty, prime two (2) bottles of Distilled Water through the Substrate System.

Appendix E: Editing Barcode IML File

Procedure for modifying barcode parameters for the laser barcode scanner.

Run the program filetransfer.exe

Press the START button

Press the RUN button in the start menu

Type c:\dpc\c\filetransfer.exe

Press OK

Copy BARCODE.IML from the control side to the user side

Click Copy Files on the menu bar

Click Control->User PC

Click From Bin Directory

Click BARCODE.IML

Click OK

Click OK to close "file transfer was successful"

Edit BARCODE.IML

Press the START button

Press the RUN button in the start menu

Type edit c:\dpc\c\barcode.iml

The third line should read:

 $\langle KrX, X, X, X, X \rangle$, where X = some number

This line determines the parameters for I 2 of 5 and follows the format

<KrA,B,C,D,E>

A (STATUS) 0 = Disable, 1 = Enable

B (CHECK DIGIT STATUS) 0 = Disable, 1 = Enable

C (CHECK DIGIT OUTPUT STATUS) 0 = Disable, 1=Enable

D (CODE LENGTH # 1) 0 to 30 (only even numbers are allowed)

E (CODE LENGTH # 2) 0 to 30 (only even numbers are allowed)

See attached sheet to modify other barcodes

Exit Editor by Pressing ALT F

Press X

Press Enter to save BARCODE.IML

Copy BARCODE.IML from the user side to the control side

Click Copy Files on the menu bar

Click User->Control PC

Click BARCODE.IML

Click OPEN

Click Bin Directory

Click OK

Click OK to close "file transfer was successful"

Click EXIT to close Control PC Utilities

SYMBOLOGY TYPES

Code 39

Format: < Kpstatus, check digit status, check digit output status, large intercharacter gap, fixed code length status, code length>

status: check digit status: check digit output status:

0 = Disabled 0 = Disabled 0 = Disabled 1 = Enabled 1 = Enabled

1 = Enabled Any number from 1 to 64

Example: To set Fixed Code Length to 30, enter $\langle Kp_{1,1}, 1, 30 \rangle$ or $\langle Kp_{1,0}, 0, 0, 1, 30 \rangle$.

Codabar

Format: <Kqstatus, start & stop match status, start & stop output status, large intercharacter gap, fixed code length status, code length, check digit type, check digit output>

status: start & stop match status: start & stop output status:

 $\mathbf{0} = \mathbf{Disabled}$ $\mathbf{0} = \mathbf{Disabled}$ $\mathbf{0} = \mathbf{Disabled}$ $1 = \mathrm{Enabled}$ $1 = \mathrm{Enabled}$ $1 = \mathrm{Enabled}$ $large\ inter-character\ gap:$ $fixed\ code\ length\ status:$ $code\ length:$ $\mathbf{0} = \mathbf{Disabled}$ $\mathbf{0} = \mathbf{Disabled}$ Default is $\mathbf{10}$

1 =Enabled 1 =Enabled Any number from 1 to 64

Check digit type: check digit output:

0 = Disabled2 = NW70 = Disabled1 = Mod 163 = Both1 = Enabled

Example: To set Fixed Code Length to 9, enter <Kq1,,,,1,9> or <Kq1,1,1,0,1,9>

I 2 of 5

<u>Format: <Krstatus, check digit status, check digit output status, code length #1,</u> code length #2>

Status: check digit status: check digit output status:

0 = Disabled0 = Disabled0 = Disabled1 = Enabled1 = Enabled1 = Enabled

code length #1: code length #2:
Default is **10**Default is **6**

Zero or any even number from 2 to 64 Zero or any even number from 2 to 64.

Example: To set Fixed Code Length #1 to 8 and Fixed Code Length #2 to 4, enter <Kr1,,,8,4> or <Kr1,0,0,8,4>.

UPC/EAN

<u>Format: <KsUPCstatus, EAN status, supplementals status, separator status, separator character></u>

UPC status:EAN status:supplementals status: $\mathbf{0} = \mathbf{Disabled}$ $\mathbf{0} = \mathbf{Disabled}$ $\mathbf{0} = \mathbf{Disabled}$ $1 = \mathrm{Enabled}$ $1 = \mathrm{Enabled}$ $1 = \mathrm{Enabled}$ (UPC must also be enabled) $2 = \mathrm{Required}$

separator status: separator character:

0 = Disabled Any ASCII character (except NUL).

1 = Enabled Default is comma (,).

Example: To change Supplementals to Required, and change Separator Character to a dash (-), enter < Ks1,1,2,1,->

Code 128

Format: < Ktstatus, fixed code length status, code length>

Status: fixed code length status: code length: 0 = Disabled Default is 10

1 =Enabled 1 =Enabled Any number from 1 to 64

Example: To enable Code 128, enable Fixed Code Length, and set Code Length to 9, enter < Kt1,1,9>

Appendix F: Linear Actuator Pump Dip Switch Settings

The following section will describe how to adjust the Volume and Drawback of the Linear Actuator Pumps if it is required.

<u>Note</u>: When checking the volume of the Substrate and Water pumps for the IMMULITE 2000, it must be checked in the "Run IMMULITE" program.

For the IMMULITE 2500, the Water Pumps volume must be checked in diagnostics using "IMMULITE 2500 Water Pump Volume Check", the Substrate Pump volume must be checked in the "Run IMMULITE" program.

How To Adjust Volume And Drawback for Water Pump

Volume

There is a label located inside the Water Pump which shows in detail what the 8 dip switches control.

Looking at the switches from left to right. Switches 1, 2, 3, 4, 5, and 8 control volume dispense

When adjusting the volume the switches are labeled 4, 8, 16, 32, 64, and 128, this correlates to microliters. So by switching "4" this will make a very slight adjustment to the volume. By switching "128" this will make the most drastic adjustment to the volume dispense.

Switching a dipswitch down, increases the volume by the value for that dip switch Switching a dipswitch up, decreases the volume by the value for that dip switch

Drawback

Looking at the switches from left to right. Switches 6 and 7 control drawback.

Drawback is measured by unscrewing the tube from the water probe and looking at the drawback after each dispense while running water probe prime diagnostic. 1/8" is optimal.

By switching the rocker switches (number 6 and/or 7) down you will increase the drawback, and by switching the rocker switches up you will decrease the drawback.

How to Adjust Volume and Drawback for Substrate Pump

<u>Volume</u>

There is a label located inside the Substrate Pump, which shows in detail what the 8 dip switches control.

Looking at the switches from left to right. Switches 1, 2, 3, 4, 5, and 8 control volume dispense

When adjusting the volume the switches are labeled 4, 8, 16, 32, 64, and 128, this correlates to microliters.

By switching "4" this will make a very slight adjustment to the volume.

By switching "128" this will make the most drastic adjustment to the volume dispense.

Switching a dipswitch down, increases the volume by the value for that dip switch Switching a dipswitch up, decreases the volume by the value for that dip switch

Drawback

Looking at the switches from left to right. Switches 6 and 7 control drawback.

Drawback is measured by unscrewing the tube from the water probe and looking at the drawback after each dispense while running water probe prime diagnostic. 1/8" is optimal.

By switching the rocker switches (number 6 and/or 7) down you will increase the drawback, and by switching the rocker switches up you will decrease the drawback.

Appendix G: Troubleshooting Discordant Results

A discordant result occurs when a customer runs a patient sample and the initial value is questioned. The same patient sample tube is once again put on the system and rerun yielding an answer that is then significantly different from the first result. This difference is sometimes enough to alter the clinical status of the patient and the treatment decisions of the physician. While it is frequently the same patient sample tube that is used for the repeat, it may be a different one. Also, the sample may have been repeated on a non-IMMULITE system, or may have been sent out to a reference lab. In that case, we may be looking at methodology differences also. Discordant results can also be attributed to the assay. In these cases the result obtained is reproducible but the value still does not fit with the clinical picture.

A Discordant Result Service Call is to be addressed by the Field Service Engineer with the utmost seriousness and attention to detail. Discordant calls impose legal and ethical implications. With this being said, the FSE should not assume the instrument is directly responsible for the discordant result. Approximately 80% of all Discordant Call investigations never result in the discovery of a root cause. If the discordant result is due to sample or operator issues, then validating the instrument performance and not finding a problem is exactly what you are expected to find.

- 1. The FSE, when dispatched to a customer site for a discordant issue, must launch a detailed customer data investigation once onsite revealing the exact nature of problem:
 - A. Low CPS values or High CPS values on patient results when compared to sample rerun? In other words, which result is bad and are we losing or adding counts? This applies only if the sample is run more than twice
 - B. Test Type (sandwich, competitive, etc...) and sample volume.
 - C. Is the issue focus on one discordant result or more than one?
 - D. If multiple discordant results are being investigated, do they involve the same assay or different assays? List the assays. Do the assays on the list have anything in common with one another such as test type, mechanical movement of the reaction tube through the system, or sample volume?
 - E. Is the QC data in range for all assays on the system including the assay in question?
 - F. Has the customers readjusted the assay in an attempt to resolve the problem themselves?
 - a. Look at the adjustment CVs and one month of adjustment history for the assay in question. Is there a trend shift or a loss of precision?
 - G. Is the discordant related to a dilution or a pretreatment and were these done by the instrument or the operator?
 - H. What type of test tubes is the customer using? (microsample, plastic, glass, primary, secondary) Is there a false bottom, insert, glass beads in the sample or are the tubes pulled up to defeat the dead volume settings?
- 2. Discordant results may involve a precision issue with the assay or the instrument in general. A precision test must be performed on the instrument using the assay in question to validate that the system performance meets factory standards. The results of this precision test using 20 reps of patient sample and tri-level controls (20 reps of each level) should be entered into the precision worksheet provided to calculate CVs and to then compare variability to package insert claims.

- 3. If the precision test yields high CV results (based on PI claims and / or kit release data available through DPC Technical Service), other similar assays should be tested. For example, choose a similar test method (sandwich, competitive, or sequential), similar sample volume size and similar CPS result ranges if at all possible. This will tell you if the imprecision is isolated to one assay type or is seen across the board on the system.
- 4. Determine if the system is experiencing a general precision issue affecting a number of assays (or all assays to some degree). This can be accomplished by picking several assays and comparing their QC CV's to the package insert claims. Also review adjustment CPSes and CVs.
- 5. If the precision is repeatedly in proper range, try to determine if the patient sample tube caused a short sample aspiration, (e.g., bubbles). In other words, investigate the actual patient sample source for clues as to the cause of the discordant result.
- 6. A SPY FILE investigation should be performed by technical service for level sense problems, sample or reagent. Review the results of this SPY File investigation. This should have been done before an FSE was dispatched on the call. Verify the results of this SPY FILE investigation through Clientele or direct contact with DPC Tech Service.
- 7. A water test should be performed to eliminate Alkaline Phosphatase contamination as a contributing factor.
- 8. If the system is found to have a precision issue, the precision problem should be troubleshot using the checklist provided below.
- 9. The precision problem is eventually identified and resolved. **It is important to note here that in the majority of cases, root cause of a single discordant result may never be identified and may lie in the sample or an operator influenced phenomenon in the form of a single non-reproducible event. In such a case, you as the FSE must verify the performance of the system by running precision studies and eliminating the system as the cause of the discordant result. A general precision problem across multiple assays is generally a problem that must be resolved and may in fact be instrument related. However, in the case of single discordant results that cannot be reproduced where the system is now yielding good CVs on precision testing, it is perfectly acceptable to conclude that the system meets our performance standards and root cause is outside the realm of the system.
- 10. Final precision test results are shared with the customer to prove the resolution has been successful or the system meets our acceptance criteria. This precision testing should include patient samples for the particular assay in question in addition to controls.
- 11. DPC Field Service and Technical Service are one team. Do not hesitate to ask a Technical Service Specialist to speak directly to your customer in cases where issues become extremely technical in nature, or are out of the area of your expertise.

Precision Troubleshooting Checklist

■ System water contamination or PH issues

- o A contaminated water supply can lead to imprecision.
- The water source as well as water from different sections of the IMM2000 should be tested for contamination.
- The watertest diagnostic is only showing Alkaline Phosphatase contamination. The customer's water supply may pass this test and still be contaminated in a way that negatively impacts assay results.
- o Sometimes it is the water bottles or "carboys" that are contaminated.

□ Reaction Tube supply contamination

o If the customer's supply of reaction tubes has been exposed to any foreign material (e.g., sprays, powders or excess moisture and mold), this could contribute to a precision issue.

□ Patient Sample

- o Fibrin in sample could cause imprecision due to partial probe occlusion.
- Bubbles in sample can cause short sampling.
- o Hemolyzed (reddish looking) sample could cause imprecision.
- o Frozen aliquot samples and QC material must sit for ½ hour after completely thawed to allow proper reconstitution and stabilization of sample.
- o Gel barrier angle caused by centrifuge buckets that stick and don't swing completely horizontal can contribute to gel barrier aspiration (gel too high).

□ Sample and Reagent Probe Angle out of range

O The dispense stream should be as straight as possible when it covers the bead in the reaction tube. A significant angle on the dispense stream can lead to one side of the bead not being completely coated with sample.

☐ Sample and Reagent Probe surface contamination or wicking

o If the outside tip surface of the probe has a residue buildup or possible gel barrier coating, there will be a wicking effect where fluid will form a drop that sticks to the outer tip of the probe due to the surface adhesion properties. This issue can absolutely contribute to imprecision.

□ Sample and Reagent Probe occlusion / internal damage

- If the small inner diameter of the probe becomes occluded to any degree, say in the case of gel barrier aspiration, the samples drawn from this probe will be subject to inconsistent volumes and cross contamination. Both of these properties are imprecision contributors.
- Any object inserted onto probe in an attempt to clear a clot will cause damage, contamination, carry-over and increased imprecision.

□ Sample and Reagent Probe aspiration positioning

If the probes are not centered in the openings of the patient tube or reagent wedge, it is entirely possible for the probe to "short sample" (last part of aspiration is air). Fluid in a test tube column forms a meniscus where the fluid at the immediate inner circumference curves upward due to capillary action. If the probe is positioned to aspirate near the inner edge of the test tube, the level sense point is too high and short sampling can occur.

□ Bubbles in the patient sample tube or the reagent wedge (Level Sense Issues)

This issue will also cause short sampling and lead to a precision problem and discordant results. It is a good idea to check all reagent wedges for bubbles. Multiple wedges with bubbles could indicate improper handling on the part of the operator. Numerous reagent wedges with removed glides in the reagent carousel may be indicative of problems with foam or bubbles.

□ Sample and Reagent Probe dispense positioning

The height of the probes from the top of the bead at the dispense position is a critical distance. Pretreated assays, such as VB12 and Folate, pre-treat the patient sample in a reaction tube with no bead. After circling the incubator once, the probe will descend into this pretreated sample and attempt to aspirate the correct sample volume. Since the level sense PCB does not function in this process, we rely on the "Z" depth sample probe configuration setting as a starting point for determining where the probe begins to aspirate sample. If this setting is too high, the probe will not set deep enough in the fluid and will short sample or draw some volume of air.

☐ Sample and Reagent Probe cleaning and carryover

- o If the previous sample induced a clot that was not properly cleaned, the resulting carryover potential can contaminate subsequent samples and contribute to discordant results.
- o It is critical to the proper operation of the system that the probes remain clean. There are many factors that provide for this including:
 - Daily probe clean diagnostic
 - Adequate probe wash fluid supply
 - Proper position of the probe in the blind hole (fluid must spiral up the probe to efficiently wash)
 - Damaged Probes

□ Reagent and Sample probe fluid connections integrity

- The fluid connectors must be hand tight on the manifold block or precision will not be maintained. Evidence of leaking probes shows up as peppered droplets of dried chemistry residue found along the arc path of the probes.
- O Check to be sure there is not a leak where the tubing connects to the top of the probe. A leak here will show up as a small volume of fluid trapped in between the inner and outer tubings near the break point. This problem could be caused by lack of slack and strain relief on the probe tubing leading to an eventual break in the line. A probe in this condition must be replaced.
- O It has also been discovered that in cases where the probe connections at the black standoff are over tightened, the acrylic manifold block can crack and leak yielding imprecise aspiration volumes and results. The manifold in this case must be replaced.

□ All Tubing should be tight and leak free

- o There should be no signs of leakage or bubbles in fluid lines.
- All fluid connectors should be tight, but not over tightened to the point of inducing damage to the connectors or manifold blocks.

□ Clot Detection Issues

o It is possible for fibrin in the sample to interfere with the aspiration by partially occluding the probe without the system flagging the event as a clot. This could potentially yield a short sample volume and discordant result.

□ Sample and Reagent Manifold Valve Integrity

o The manifold valves should be leak free and fully functional.

□ Ceramic Rotary Valve Integrity

o The ceramic valves should be leak free and fully functional.

□ Dual Resolution Dilutors

- o The dilutors are directly responsible for accuracy and precision.
- O Verify seal integrity and / or replace seals as needed.
- o DRD nuts must be properly tightened with no acrylic block movement.

☐ Incubator Chain Alignment

- The incubator chain intake and output positions for reaction tubes must be adjusted properly to prevent the tubes from being knocked over by hitting the edge of the baffles and splashing fluid.
 This splashing is a visual representation of imprecision.
- O Dried chemistry residue has been known to "flake" off and fall into the reaction tubes as they are shaken and incubated.

□ Shaker Bar Height

- If the shaker bar height in the Incubator and / or the Luminometer is too low, the degree of shaking experienced by the reaction tubes will be too low or non-existent.
- o If the shaker bar height is set too high, the degree of shaking will be too abrupt causing splashing and leading to imprecision and inaccuracy.

☐ Splashing in General

 Any dried chemistry residue found anywhere along the reaction tube path in the tube processor is evidence of splashing and a visual representation of imprecision. The cause must be identified and resolved.

□ Wash Station Efficiency

- The reaction tube is brought up and into the wash station by the tube lifter asm. The tube is then spun to eliminate the fluid inside and subsequently washed several times with clean distilled water. This process is critical to ensure accurate and precise results.
- O Verify that the tube lifter spring tension applied to the reaction tube is sufficient (1/8" to 1/4" compression) to ensure the reaction tube spins while pressed onto the high-speed spinner spline.
- o If the spline teeth on the high-speed spinner are completely occluded with material, the tube will not empty properly and your results will be affected by the bad wash.
- o Bacterial growth in the wash sump or on the spline surface can lead to sample contamination.
- Verify that the Waste Tube Cleaning Diagnostic is being performed routinely. Any solid matter buildup on the inner surface of the sump proves that the diagnostic cleaning is not being performed.

□ Vacuum Waste Elimination

- Vacuum Pump function and liquid waste elimination in the sump is also critical to the accuracy and the precision of results.
- o Ensure the vacuum pump is pulling adequate vacuum (>18" Hg).
- o An inaccurate vacuum level could cause the sump to overflow and possibly spill waste fluid back into the reaction tubes.
- o Any liquid remaining in sump is a sign of problems and must be investigated and eliminated.

□ Water Pump Dispense Volume

- The water pump dispense volume (400 uL +/- 20 uL) is critical in ensuring that the washing of the bead is effective. If this water volume is either too low or inconsistent (over 10 replicates), the system will be unable to yield precise results.
- o Inaccurate or imprecise pumps should be replaced.
- O Suck back adjustment should be verified and / or corrected.

□ Substrate Pump Dispense Volume

- The substrate pump dispenses 200 uL of substrate into the reaction tube after it is washed. If the volume of liquid substrate is either too low or inconsistent (over 10 replicates), the system will also be unable to yield precise results.
- o Inaccurate or imprecise pumps should be replaced.
- Suck back adjustment should be verified and / or corrected. Due to the extended spiral tubing imbedded in the substrate probe, suck back must be measured with the probe installed.

□ Substrate Issues in general

- o It is important that the liquid substrate be free from contamination. The pump may require decontamination with NaOH if the pump bellows become contaminated. If the Substrate supply is contaminated, it must be discarded and replaced after decontaminating the reservoir bottle.
- The substrate dispense probe may also be contaminated. The substrate line decon described above should correct this situation.
- o It is also important that the substrate supply in the reservoir be unexposed to CO2, hence the presence of a functioning CO2 Scrubber.
- o It is also critically important that the Substrate Reservoir CO2 Scrubber be inverted (breather filter side up) and the associated tubing is free from occlusions such as pinched or kinked areas or anything that may cause the pump to pull a vacuum on the reservoir. This condition will lead to inaccurate substrate dispense volumes or eventually no substrate being dispensed.
- o WATERTEST 15 is used routinely to discover substrate line contamination.

□ Luminometer Chain Alignment

The alignment of the Luminometer Chain is critical to the precision and accuracy of results. Since the Luminometer Chain essentially aligns the tubes in front of the PMT to be read, any inaccurate or inconsistent positioning will influence the results and lead to imprecision.

□ Luminometer Shutter function

- The Lum Shutter descends onto the reaction tube where it is read at the PMT and isolates the reaction tube from adjacent tubes to prevent "cross talk" or light from the other reaction tubes influencing the readings at the PMT.
- o If the shutter "down" position is set too high or is inconsistent, this will contribute to imprecision.
- o Any presence of stray ambient light will negatively impact results.

□ PMT Voltage Stability

The integrity of the PMT power supply will influence the performance of the PMT (Photo multiplier Tube). If the voltage is out of factory specification or unstable, it must be replaced.

□ Attenuator Wheel

The attenuator wheel filter is used to read CPS counts above one million and reduce the light intensity (similar to sun glasses) to a point where the sample can be read in the linear working range of the PMT. The positioning of the Attenuation Filter, the "open" hole and the "closed" area on the wheel used to read attenuated and unattenuated samples must be accurate and consistent.

□ Reagent Issue

- Reagents used in the system must be kept at refrigeration temperatures while in storage. While in
 use, they must not be subject to contamination. For example, the probe cleaning must be totally
 effective in preventing cross contamination of the reagents.
- o Contaminated reagent can contribute to imprecision issues.
- o Long periods of non-refrigeration during shipment can negatively impact kit performance.

□ Bead Issues

o Although highly unlikely, it is entirely possible for the bead supply to contribute to imprecision from issues like contamination, high humidity, etc.

□ Dilution Well Issues

- o If a precision issue can be narrowed down to only include assays or samples that are being diluted, then the configuration settings and speeds of the dilution well should be investigated.
- The dilution well insert can also be replaced if contaminated. Contaminates may include gel
- o Inconsistent or inaccurate dilution well mix speeds may cause sample, diluent and water concentrations to change due to loss volumes (spillage).

□ Temperature Issues

- There are three critical variables in the processing of chemical reactions within the tube processor, Time (elapse time from dispense point to PMT read), Mixing (the degree of mixing the tubes are exposed to for this time), and Temperature (the temperature at which the tubes are exposed during this same time frame).
- o If the temperature is either inaccurate or inconsistent, the system will not yield precise results.

□ Customer Induced Issues

Overwritten accession numbers – Customer may mistakenly overwrite an accession number before sampling occurs thereby confusing sample results and identifying results with the wrong patient. This error is quite common.

□ Detailed Error Log Investigation

There are times when the detailed error log can provide vital clues as to the nature of questionable results. Review the time and date range of the results in question making sure to include the complete cycle time up to and shortly before the actual sampling. Watch for "low water", "low probe wash" and "low substrate" errors or any error that can influence results such as DRD jams and temperature errors.

□ Something Missing?

- o No Substrate, CPS results will be <100
- o No Reagent, CPS results will be <10,000
- o No Bead, CPS results will be in 8,000 to 20,000 range depending on assay

□ TSH Zero Test

- Running twenty reps of the low TSH adjuster is a diagnostic tool that shows the presence of nonspecific binding. It will pick up the presence of splashing, carryover, wash quality and suck back issues.
- o CV of the CPS should generally be below 10% and normally will fall into the 5-6% range.
- o CV results at 25% and above is usually indicative of a problem.

Chemistry Troubleshooting Categories

Symptoms

System Water Contamination X X X Reaction Tube Contamination X X X Fibrin in Patient Sample X X X Bubbles in Patient Sample X X X Hemolyzed Patient Sample X X X Rushing frozen samples X X X Gel Barrier aspiration X X X Sample probe angle issue X X X Probe wicking / surface contamination X X X Sample probe occlusion / damage X X X Reagent probe occlusion / damage X X X Reagent probe occlusion / damage X X X Probe dispense positioning X X X Bubbles in Reagent Wedge X X X Probe dispense positioning (too high) X X X Fluidic tubing leaks X X X Clot detector failure X X X				
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1 competitude 1550c5	Temperature Issues		X	X

Note: Low and hi CPS refers to sandwich assays only.

General Rules of Thumb

Symptom Area to Investigate

Sandwich Assays with Low CPS results System Front End, including Pipetting, Fluidics, etc.

Sandwich Assays with Hi CPS results

System Back End, including processor, washing,

substrate, etc.

Sandwich Low CPS, Competitive Hi CPS

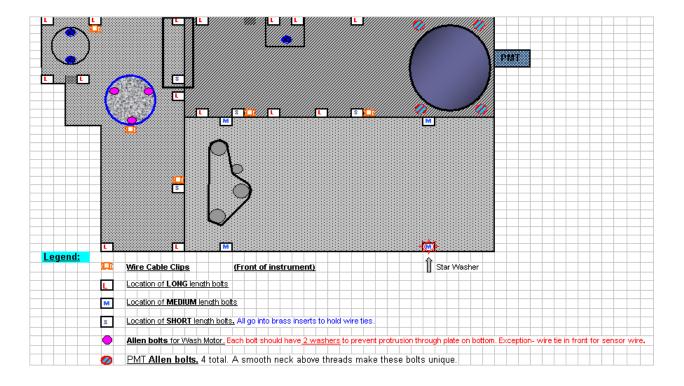
Sample Volume specific issue

Sequential Sandwich Assay with 1/2 normal CPS on adjusters, results

Reagent Manifold, probe wash getting into sample.

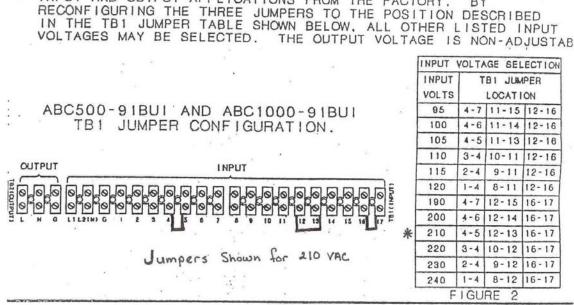
Valve Issue.

Appendix H: Hardware Location for IMMULITE 2000 Tube Processor



Appendix I: **Jumper Configurations for Step Down Transformer**

THE POWER CONDITIONER IS READY TO INSTALL FOR 120VAC INPUT AND OUTPUT APPLICATIONS FROM THE FACTORY. RECONFIGURING THE THREE JUMPERS TO THE POSITION DESCRIBED IN THE TB1 JUMPER TABLE SHOWN BELOW, ALL OTHER LISTED INPUT VOLTAGES MAY BE SELECTED. THE OUTPUT VOLTAGE IS NON-ADJUSTAB



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